


CardinalHealth
NATIONAL ACCOUNT/CHAIN PHARMACY QUESTIONNAIRE
 Pharmaceutical Distribution

I. NATIONAL ACCOUNT/CHAIN PHARMACY HEADQUARTERS

1. Pharmacy Name	<u>CVS</u>
2. DBA (if any)	<u>CVS/PHARMACY #</u>
3. National Account/Chain Pharmacy Headquarters Address	<u>One CVS Drive, Woonsocket, Rhode Island 02895</u>
4. National Account/Chain Pharmacy Headquarters Phone	<u>401-770-9344 or 1-800-746-7287</u>
5. Name of Principle owner(s) or Corporate Entity	<u>CVS Corporate – CVS Shareholders</u>
6. Ownership type (check one)	<input type="checkbox"/> Sole proprietor <input checked="" type="checkbox"/> Corporation <input type="checkbox"/> Other
7. Owner(s) name or contact person for the Organization and their title ("Contact Person")	<u>Stephen Signes - Advisor/Rx Ops</u>
8. Owner's or Contact Person's Business Address	<u>Same as corporate address.</u>

Rev. 1/15

 PLAINTIFFS TRIAL
 EXHIBIT

P-42123_00001


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 Pharmaceutical Distribution

9. Owner or Contact Person's Phone	<u>(401) 770-5907</u>
10. Organizational contact person at the National Account/Chain Pharmacy that Cardinal Health may contact regarding anti-diversion activities or threshold events (if different than questions 7-9 above)	Name: <u>Stephen Signes</u> Title: <u>Advisor/Rx Ops</u> Phone: <u>(401) 770-5907</u> Email: <u>Stephen.signes@cvshealth.com</u>
11. Are any of Principle Owner's or Corporate Entity's current DEA registrations suspended or revoked?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
a. If yes, provide details (attach documentation including public records)	<u>2 CVS stores in Sanford – 219 and 5195</u>
12. Is there a record available of the Principle Owner or Corporate Entity being convicted of a crime relating to distribution of prescription drugs, or listed chemicals?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
a. If yes, provide details (attach documentation including public records)	


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II. NATIONAL ACCOUNT/CHAIN PHARMACIES THAT WILL BE SERVICED

13. DEA Registration Number:	multiple
14. Has Cardinal Health verified the DEA registered name of the pharmacy prior to shipment of controlled substances and/or listed chemicals?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
15. Has Cardinal Health verified the DEA registered address of the pharmacy prior to shipment of controlled substances and/or listed chemicals?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
16. Has Cardinal Health verified the validity of pharmacy's DEA Registration prior to the shipment of controlled substances and/or listed chemicals? This information can be confirmed at www.deadiversion.usdoj.gov/webforms/validateLogin.jsp , www.deanumber.com , or the key contact person or his/her designee at the National Account/Chain Pharmacy.	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
17. State Registration Number:	multiple
18. Has Cardinal Health verified the state registration(s) of the pharmacy prior to shipment of controlled substances and/or listed chemicals? This information can be confirmed at the pharmacy's respective state licensing board website, where available, or the key contact person or his/her designee at the National Account/Chain Pharmacy.	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO


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III. PRIOR HISTORY OF PHARMACIES THAT WILL BE SERVICED

19. Is the DEA registration(s) of any of the National Account/Chain Pharmacy's pharmacies suspended or revoked?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
a. If yes, provide details (attach documentation including public records if available)	<u>CVS/Pharmacy #219, 3798 Orlando Drive, Sanford, FL 32773, and CVS/Pharmacy #5195, 4369 W. 1st Street, Sanford, FL 32771 -</u> http://www.dea.gov/divisions/mia/2012/mia091212.shtml
b. If yes, is there any evidence that the conduct that led to suspension or revocation is ongoing or that the registrant has failed to take adequate corrective measures?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO If 'Yes,' please explain: _____
20. Has Cardinal Health been notified that other wholesalers ceased shipping or restricted purchases of controlled substances to any of these pharmacies because of a concern of diversion?	<input type="checkbox"/> YES <input checked="" type="checkbox"/> NO
a. If yes, provide details (attach documentation including public records if available)	
21. Has a Google Web Search been performed on behalf of this DEA Registrant?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
a. Did the Google Web Search result in any details supporting adverse or criminal activity involving the account, any details indicating the diversion of controlled substances occurred, or any details supporting the suspension or revocation of the pharmacy licenses or any	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO


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 Pharmaceutical Distribution

individual licensees (attach documentation from web search)?	
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IV. SOM AND ANTI-DIVERSION PROGRAM

22. Has the National Account been notified of DEA's expectations of wholesalers regarding suspicious order reporting as set forth in one or more of the three letters sent to registered manufacturers and distributors from DEA's Deputy Assistant Administrator, Office of Diversion Control, dated September 27, 2006, February 7, 2007 and December 27, 2007?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
23 Has National Account been offered copies of Cardinal Health educational material concerning a pharmacist's corresponding responsibility and the web link to NABP/ADIWG/Cardinal Health "Red Flag" video found at http://cardinalhealth.com/us/en/MedicationSafety/RedFlags to help educate their pharmacists on their corresponding responsibility?	<input checked="" type="checkbox"/> YES <input type="checkbox"/> NO

V. ADDITIONAL COMMENTS

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COMPLETED BY: Jason Gawlik, Ashlee Hamski, Alana Millonzi, Mollie Hill-Turner
 (Name /Title)

State of Rhode Island Department of Health			
STEPHEN E SIGNES			
License No:	RPH04896	Profession:	Pharmacy
License Type:	Pharmacist		
License Status:	Active	Issue Date:	2/9/2010
Expiration Date:	6/30/2016		
Secondary License Type:			
Education Information			
School Name:	MASSACHUSETTS COLLEGE OF PHARMACY		
Graduated:			
Specialty Information			
No Specialty Information			
Disciplinary Action			
Disclaimer: The individual license information on the Licensee Lookup displays only the current license status (e.g., Active, Active Probation, Suspended, Revoked). For the disciplinary history of any individual licensee, please click on the link for the specific profession and then on the Disciplinary Actions link available on each professional board's webpage.			
See Board Disciplinary Listings at http://www.health.ri.gov/lists/disciplinaryactions			
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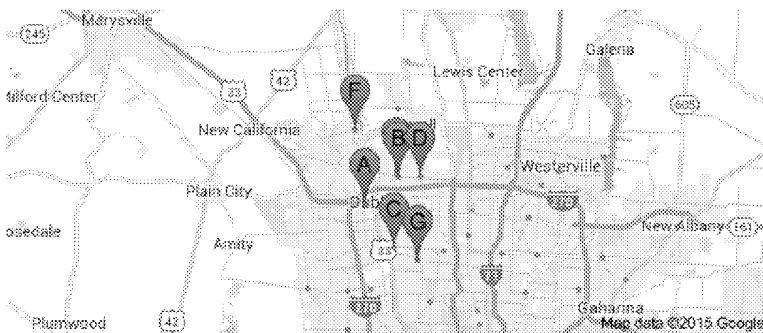
Store #6150 Details ... TO Store #6150 305 West Bridge Street ...

Pharmacy

Rapid Refill - New Prescriptions - CVS.com account - ...

Dublin #6161

TO Store #6161 7470 Sawmill Road, Dublin, OH 43016 ...

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Star Local Media - 16 hours ago

CVS Pharmacy

Pharmacies and drug stores company



CVS Pharmacy is an American pharmacy retailer and currently stands as the second largest pharmacy chain, after Walgreens, in the United States, with more than 7,600 stores, and is the second largest US pharmacy based on total prescription revenue. Wikipedia

Customer service: 1 (800) 746-7237**Technical support:** 1 (888) 607-4267**Headquarters:** Woonsocket, RI**CEO:** Larry J. Merlo**Parent organization:** CVS Health**Founders:** Stanley Goldstein, Ralph Hoagland, Sidney Goldstein**People also search for**

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<https://itunes.apple.com/us/app/cvs-pharmacy/id395545555?mt=8> ▾

★★★★★ Rating: 3.5 - 182 reviews - Free - iOS

Oct 14, 2015 ... Description: The official **CVS/pharmacy** iPhone App puts

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CVS Pharmacy - Wikipedia, the free encyclopedia

https://en.wikipedia.org/wiki/CVS_Pharmacy ▾

CVS Pharmacy (styled as **CVS/pharmacy** or simply **CVS**) is an American pharmacy retailer and currently stands as the second largest pharmacy chain, after ...

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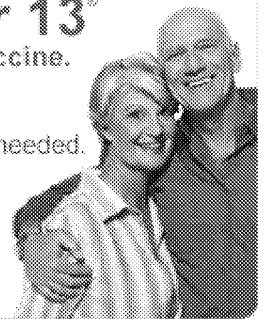
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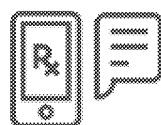
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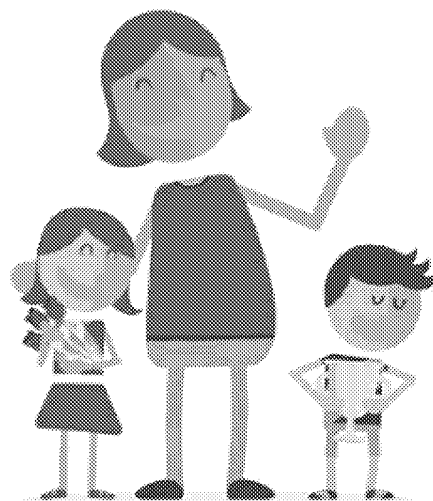


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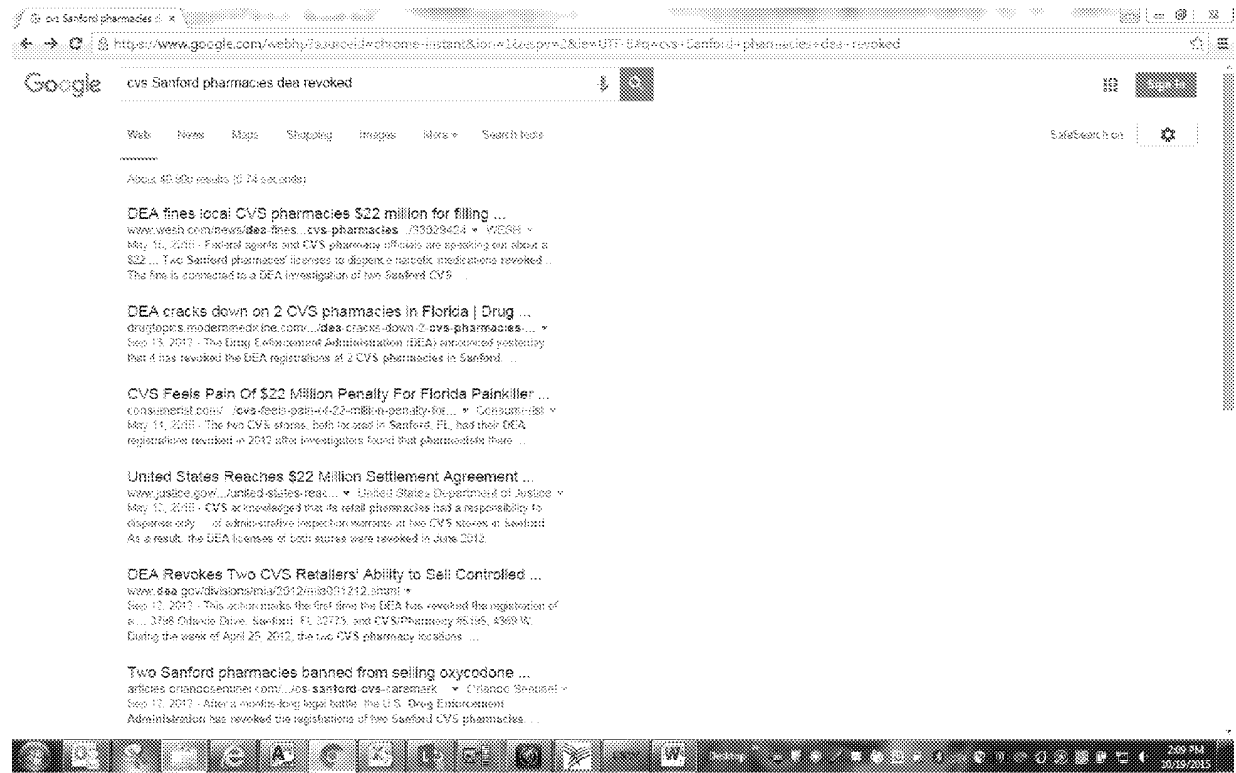




NATIONAL ACCOUNT/CHAIN PHARMACY QUESTIONNAIRE

Pharmaceutical Distribution

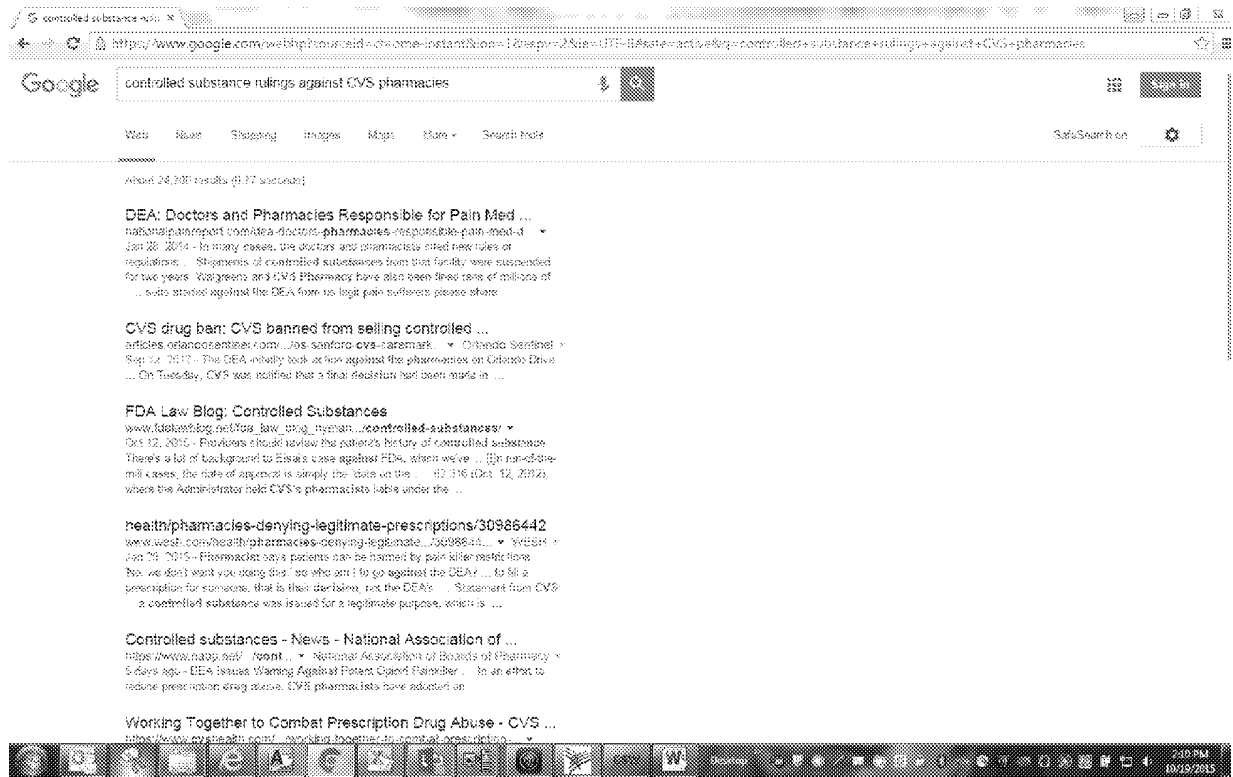
Google Screenshots:





NATIONAL ACCOUNT/CHAIN PHARMACY QUESTIONNAIRE

Pharmaceutical Distribution



MIAMI NEWS

September 12, 2012
 Contact: Public Information Officer
 Number: 954-660-4602

DEA Revokes Two CVS Retailers' Ability To Sell Controlled Substances

MIAMI, FL. – Mark R. Trouville, Special Agent in Charge of the Miami Field Division, Drug Enforcement Administration (DEA), announced today the revocation of DEA Registrations at two CVS Pharmacies located in Sanford, Florida. This action marks the first time the DEA has revoked the registration of a registrant that is part of a large national chain.

On February 4, 2012, the DEA served an Immediate Suspension Order (ISO) at Holiday C.V.S., L.L.C., doing business as (d/b/a) CVS/Pharmacy #219, 3798 Orlando Drive, Sanford, FL 32773, and CVS/Pharmacy #5195, 4369 W. 1st Street, Sanford, FL 32771. An ISO is served pursuant to 21 U.S.C. § 824(d) when a DEA-registered business or individual ("registrant") constitutes an imminent danger to the public safety and DEA suspends that registrant's ability to handle or distribute a controlled substance such as oxycodone, hydrocodone and others pending a judicial proceeding.

During the week of April 25, 2012, the two CVS pharmacy locations were given an opportunity for an administrative hearing to determine whether the DEA Certificate of Registration at each of the two locations should be revoked. On June 8, 2012, the Chief Administrative Law Judge (AJL), Judge John J. Mulrooney II, issued a recommendation to revoke both CVS Pharmacy #219 and CVS Pharmacy #5195 DEA registrations based on the evidence presented during the hearing.

On August 31, 2012, DEA Administrator Michele M. Leonhart issued the Final Order to revoke both registrations as recommended by the ALJ. The order also denies any pending applications of Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #219 and #5195. The order is effective 30 day from the date of publication in the Federal Register. The ISO will remain in effect until then.

"The Final Order issuance reflects the continued commitment of the DEA to identify and bring to light the diversion of controlled substance pharmaceutical drugs," said DEA Special Agent in Charge Mark R. Trouville. "The DEA Miami Field Division will stay the course until this diversion is no longer a problem in Florida."

These actions are part of the DEA Miami Field Division's continuing efforts to combat the state's prescription drug abuse epidemic and its role as a major source of diverted pharmaceutical drugs to other states. On average, seven people die every day in Florida due to prescription drug abuse, according to the Florida Department of Law Enforcement. The DEA Miami Field Division's efforts in recent years have included arrests and administrative and criminal actions against Florida doctors and individually owned pharmacies and pain clinics that operated outside the scope of legitimate medical purposes.

More than seven million Americans abuse prescription drugs, according to the 2010 Substance Abuse and Mental Health Services Administration's National Survey on Drug Use and Health. And every day, on average, 2,500 teens use them to get high for the first time, according to The Partnership at Drugfree.org.

Other DEA Miami Field Division's efforts go beyond regulatory administration and enforcement operations. The MFD has participated in numerous prescription drug abuse awareness seminars, as well as training and educational conferences for doctors and pharmacists. On February 28, 2011, the Miami Field Division established a 24-hour "Pill Mill" tip line, which allows callers to leave information about a doctor or clinic that concerns them. The toll-free number is 1-888-954-4662, or members of the public can send an email to Florida.Pill.Mill.Tips@usdoj.gov. In addition, the Miami Field Division has registered over 100 collection sites all over Florida for people to dispose of unused, unwanted or expired prescription drugs during the 5th DEA National Prescription Drug Take-Back Day occurring on September 29, 2012. Go to www.dea.gov or call 800-882-9539 to find a collection site near you.

###



FEDERAL REGISTER

Vol. 77

Friday,

No. 198

October 12, 2012

Part II

Department of Justice

Drug Enforcement Administration

Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195; Decision and Order and Denial of Request for Redactions; Notices

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

[Docket Nos. 12–37 and 12–38]

**Holiday CVS, L.L.C., d/b/a CVS/
Pharmacy Nos. 219 and 5195; Decision
and Order**

On June 8, 2012, Chief Administrative Law Judge (ALJ) John J. Mulrooney II, issued the attached Recommended Decision. Both parties filed Exceptions to the ALJ's decision.

Having considered the record in its entirety, including the parties' Exceptions, I have decided to adopt the ALJ's recommended rulings, findings of fact (except as discussed below), conclusions of law, and proposed sanction. A discussion of Respondents' Exceptions follows.¹

Respondents' Exceptions

Respondents raise numerous exceptions to the ALJ's Recommended Decision. Of their contentions, the most substantial, but ultimately still unpersuasive, are the following:

(1) That their conduct in dispensing controlled substance prescriptions issued by two physicians, whose DEA Registrations were "expired" and therefore invalid, "cannot serve as a basis for revocation," Resp. Exceptions at 2–9;

(2) that the ALJ's findings that Respondents dispensed controlled substances pursuant to prescriptions, which raised red flags that a pharmacist could not resolve, and thus violated their corresponding responsibility under federal law, are not supported by substantial evidence, *id.* at 9–22; and

(3) that the ALJ failed to consider evidence of their acceptance of responsibility, *id.* at 22–25.

Exception One—Respondents' Dispensings of Controlled Substance Prescriptions Issued by Physicians Whose Registrations Were "Expired" Does Not Support the Revocation of Their Registrations

The evidence showed that both Respondents dispensed numerous prescriptions which were issued by two physicians, Dr. Anthony Wicks and Dr. Ronald Lynch, who no longer held their DEA registrations and thus could not lawfully prescribe controlled substances under federal law. See 21 CFR 1306.03(a) ("A prescription for a controlled substance may be issued only by an individual practitioner who is * * * [e]ither registered or exempted

from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter."'). More specifically, with respect to Dr. Wicks, the evidence showed that his registration expired on May 31, 2011. Yet, between June 6 and July 15, 2011, Respondent CVS #219 dispensed thirty-eight prescriptions issued by Dr. Wicks for oxycodone 30 mg. Likewise, between June 7 and July 14, 2011, Respondent CVS #5195 dispensed seventeen prescriptions issued by Wicks for oxycodone 30 mg.

While Respondent also characterizes Dr. Lynch's registration as "expired," the record shows that Lynch's registration had, in fact, been revoked following a hearing under 21 U.S.C. 824(a). More specifically, on December 3, 2010, the Agency issued a Decision and Final Order, which revoked Dr. Lynch's registration with an effective date of January 18, 2011, based, *inter alia*, on findings that he violated 21 CFR 1306.04(a) by issuing controlled substance prescriptions outside of the usual course of professional practice and which lacked a legitimate medical purpose; this decision was published in the **Federal Register** on December 16, 2010. GX 31; see also *Ronald Lynch, M.D.; Revocation of Registration*, 75 FR 78,745, 78,752–54 (2010). Pursuant to Agency practice, the decision was also published on the DEA Office of Diversion Control's public Web site.

Nonetheless, Respondent CVS #219 dispensed forty controlled substance prescriptions and Respondent CVS #5195 dispensed five controlled substance prescriptions, which Lynch issued after his registration had been revoked.² GX 32. The evidence further shows that CVS #219 dispensed fifteen controlled substance prescriptions issued by Lynch during or later than June 2011, and that it did so as late as September 2011. *Id.*

Respondents argue that their dispensings of the prescriptions issued by Drs. Wick and Lynch cannot support the revocation of their registration because there is "no evidence that the allegedly expired status of any prescriber's DEA registration was *known or should have been known* to Respondents or their pharmacists prior to dispensing." Resp. Exceptions, at 2. In support of their contention, Respondents maintain that the evidence shows "that every CVS pharmacist relies on the company-wide pharmacy information management system to notify the pharmacist of the status of a physician's DEA registration." *Id.*

² Having reviewed the spreadsheet, I arrive at a different number of prescriptions for each pharmacy than the ALJ did.

Respondents also argue that the database they used may have contained inaccuracies, because at the time of the dispensings, the stores were allowed to input prescriber information into the dispensing software and this information may have been inaccurate; alternatively, they argue that there was a time lag between the date on which a practitioner's registration expired and the date this information, which is collected by a third-party data aggregator, was downloaded into the company-wide pharmacy information management system.

As the ALJ noted, the argument only takes Respondents so far because the evidence shows that the third-party vendor from whom CVS receives registration data obtains its data from the Government on a weekly basis and then transmits the data to CVS on a weekly basis.³ ALJ at 60–61. Thus, while this delay might justify Respondents' having filled some of Dr. Wicks' prescriptions, it does not justify Respondents' having filled a substantial portion of them.⁴

Even if I accepted Respondents' contention that the time lag in their obtaining of updated information regarding the expiration of Dr. Wicks' registration explains why they continued to dispense his prescriptions,

³ The evidence also showed that a number would appear in the Government's database as expired on the day its registration expires.

⁴ As for the contention that the data may have been inaccurate because of information inputted at the local stores, it is not clear why personnel at local stores would be entering into the database information as to the expiration date of a practitioner's registration. While a DEA registrant is required to include his/her registration number on a controlled substance prescription, he/she is not required to include the expiration date of his/her registration on a prescription, and in the Agency's experience, it is not a customary practice among physicians to include the expiration date of their registrations on a prescription. As Respondents' witness, who serves as Vice President of Pharmacy Operations of CVS Caremark, the holding company which owns Respondents, testified, CVS has a contract with a company (HMS) which aggregates prescriber information and that it is important to aggregate prescriber data "for consistency purposes" because "[i]t allows us to have one record for each prescriber and prevents to the greatest degree possible having incorrect information tied together." Tr. 1241–42.

While this official testified that prior to April 2012, the pharmacy teams would also enter prescriber information, his testimony was to the effect that "when a pharmacy team would look up a prescriber as they were entering a prescription, it would display both the HMS records, as well as some of the historical store-entered records from the past." *Id.* at 1246. Moreover, the official testified that on doing a prescriber search prior to April 2012, the information management system "would display both the HMS records as well as any historical store-entered records that were still in the system." *Id.* at 1250–51. Unexplained is why the prescriptions could nonetheless be filled if the HMS records displayed that a physician's DEA number was invalid.

¹ All citations to the ALJ's Recommended Decision are to the slip opinion as issued by him.

the argument is totally unpersuasive when applied to the prescriptions of Dr. Lynch.⁵ As explained above, the Agency published its Decision and Order revoking Dr. Lynch's registration on December 3, 2010, and the Order was effective on January 18, 2011. Yet, Respondents dispensed Dr. Lynch's controlled substance prescriptions after the effective date of the Order and did so for months thereafter. Indeed, Respondents were still dispensing his prescriptions more than six months after the date of the Order's publication.

In enacting the Controlled Substances Act, Congress created a comprehensive and closed system for regulating the distribution of those controlled substances, which have legitimate medical uses, to prevent the diversion of these substances to those who would either abuse them or sell them to those who do. See *Gonzales v. Oregon*, 546 U.S. 243, 250 (2006). One of the fundamental features of this scheme is the requirement that all persons who seek to engage in the legitimate manufacture, distribution, or dispensing of a controlled substance must first obtain a registration from the Attorney General authorizing them to do so. See 21 U.S.C. 822(a). And to protect the public from those practitioners who engage in the diversion of controlled substances, Congress authorized the

Attorney General to revoke the registration of a practitioner upon finding, *inter alia*, that the practitioner "has committed such acts as would render his registration * * * inconsistent with the public interest." *Id.* sec. 824(a)(4).

It is manifest that Respondents' conduct in filling prescriptions issued by a practitioner whose registration had been revoked undermines the Congressional scheme. Nor, given that the Order revoking Dr. Lynch's registration was published in the **Federal Register** (as well as on the Agency's Web site), can Respondents reasonably claim ignorance of it. *Cf. Fed. Crop Ins. Corp. v. Merrill*, 332 U.S. 380, 384–85 (1947) ("Just as everyone is charged with knowledge of the United States Statutes at Large, Congress has provided that the appearance of rules and regulations in the **Federal Register** gives legal notice of their contents.") (citations omitted); see also *California v. FERC*, 329 F.3d 700, 707 (9th Cir. 2003) ("Publication in the **Federal Register** is legally sufficient notice to all interested or affected persons regardless of actual knowledge or hardship resulting from ignorance, except those who are legally entitled to personal notice.")⁶

So too, those who engage in a highly regulated industry are expected to keep informed of regulatory developments which affect their industry. See *United States v. Southern Union Co.*, 630 F.3d 17, 31 (1st Cir. 2010) ("[T]hose who manage companies in highly regulated industries are not unsophisticated * * *. It is part of [a company's] business to keep abreast of government regulation."). Here, the Agency's publication of the revocation order in Lynch's case thus provided Respondents with reason to know that, effective January 18, 2011, Lynch would no longer be authorized to issue controlled substance prescriptions. See *Ralph J. Bertolino, d/b/a Ralph J. Bertolino Pharmacy*, 55 FR 4729, 4730 (1990).

⁶In response to the testimony of an Agency's Investigator that at a December 2010 meeting with various CVS representatives regarding the diversion problem, she discussed how the pharmacies could check the status of DEA registrations through the Agency's Web site, Respondents elicited testimony from the Investigator that CVS's representatives told her that its pharmacies do not have internet access. See Tr. 73. However, surely someone in the CVS corporate hierarchy has internet access and the ability to check either the Agency's Web site (or that of the **Federal Register**) to determine whether the Agency has issued any recent Decisions and Orders revoking a practitioner's registration. That Respondents continued to fill Dr. Lynch's prescriptions for months after the revocation order became final also begs the question of what information the CVS Pharmacy Management Information System displayed regarding his registration.

Accordingly, Respondents' contention that the evidence does not establish that they (or their pharmacists) had actual knowledge of the revocation of Dr. Lynch's registration is wholly unavailing. Given that Respondents continued filling Lynch's unlawful prescriptions for more than six months after the Order became effective, and in the case of CVS #219 did so repeatedly, this conduct is sufficiently egregious to support the conclusion that Respondents committed acts which render their continued registrations "inconsistent with the public interest." 21 U.S.C. 824(a)(4); *cf. United Prescription Services, Inc.*, 72 FR 50397, 50408–09 (2007) ("While filling a prescription issued by a practitioner whose registration had recently expired might be excusable, [pharmacy's] repeated filling of numerous prescriptions long after the expiration of [physician's] registration clearly was not appropriate and was unlawful.")⁷ By itself, this conduct is sufficient to conclude that the Government has made out a *prima facie* case for revocation. I therefore reject this exception.

Exception Two—The ALJ's Findings That Respondents Dispensed Controlled Substances Pursuant to Prescriptions Which Raised Red Flags That Could Not Be Resolved and Thus Violated Their Corresponding Responsibility Under Federal Law Are Not Supported by Substantial Evidence

Respondents also contend that the record does not support the ALJ's findings that they violated their corresponding responsibility under federal law to dispense only those prescriptions, which have been "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." 21 CFR 1306.04(a). Respondents take exception to the ALJ findings because they "are based solely on the testimony of the Government's Expert * * * who stated that he found certain red flags on approximately fifty of the more than 25,000 prescriptions filled by Respondents to be 'unresolvable.'" Resp. Exceptions, at 9. Respondents contend that "[n]o other witness, no case law, no Administrator decision, and no published DEA guidance supports [the Government Expert's] claims that certain red flags are 'unresolvable' on their face." *Id.* at 9–10. Respondents further argue that the testimony of the Government's Expert

⁷That Dr. Lynch's registration had been revoked and had not simply expired, renders Respondents' conduct in filling the prescriptions even more egregious.

⁵ Respondents contend that the Agency did not rely on their filling of the prescriptions issued by Drs. Wicks and Lynch in the Immediate Suspension Orders, stating that "this conduct did not figure prominently in the Government's Prehearing Statement," and that even then the Government "only raised this issue with respect to prescriptions allegedly filled for one prescriber, Dr. Wicks, and then only tangentially." Resp. Exceptions, at 9 n.5.

As for the allegations pertaining to the filling of Dr. Wicks' prescriptions, the Government's disclosure of its intent to litigate the issue can hardly be described as tangential. See Gov. Pre-Hearing Statement at 18 (ALJ Ex. 14). In addition, in its Pre-Hearing Statement, the Government provided notice that it intended to elicit testimony as to the actions that DEA had taken against various practitioners including Dr. Lynch, *id.* at 15–16, and provided further notice that it intended to introduce a spreadsheet showing Dr. Lynch's prescriptions. *Id.* at 27. Moreover, in its Supplemental Pre-Hearing Statement, the Government provided notice that it would be introducing into evidence the Agency's Final Order revoking Dr. Lynch's registration; it also again provided notice that it would introduce a spreadsheet showing the prescriptions of Lynch, which were filled at Respondents. Gov. Supplemental Pre-Hearing Statement, at 5. Pursuant to the ALJ's Pre-Hearing Ruling, each party was required to serve opposing counsel with copies of their respective exhibits in advance of the hearing and Respondents make no claim that the Government failed to do so. Thus, Respondents had adequate notice of the Government's intent to litigate the issue of Respondents' filling prescriptions, which Dr. Lynch issued after his registration had been revoked, and raised no such objection when the Government elicited testimony and introduced various documents regarding this allegation. See *CBS Wholesale Distributors*, 74 FR 36746, 36749–50 (2009).

“is unreliable and biased and cannot by itself provide sufficient evidence to satisfy the Government’s burden of proof.” *Id.* at 10. Finally, Respondents contend that “the Government’s ‘unresolvable’ red flag argument—adopted in full in the ALJ recommendation—improperly shifts the burden of proof to Respondents.” *Id.*

At the hearing, the Government presented extensive evidence showing that numerous persons, including persons who were not Florida residents, obtained prescriptions for both oxycodone 30 mg and alprazolam 2 mg from various South Florida physicians, whose offices were typically located 200 miles or more from Respondents (see GX 62), which they then presented to Respondents’ pharmacists and which Respondents filled, notwithstanding that there are numerous pharmacies between South Florida and Sanford (where Respondents are located). The evidence included multiple spreadsheets showing each Respondent’s dispensings of the oxycodone (and in some cases alprazolam) prescriptions issued by various physicians.

A principal component of the Government’s evidence was the testimony of its expert witness, Professor Paul Doering, who reviewed various dispensings made by the Respondents and opined as to whether the Respondents had complied with their corresponding responsibility to dispense only lawful prescriptions. Professor Doering, who has been a registered pharmacist in the State of Florida since 1973, currently holds the title of Distinguished Service Professor of Pharmacy Practice, Emeritus, of the College of Pharmacy at the University of Florida, and has been on its faculty since 1976. GX 6, at 1–2. He has also published extensively and presented numerous papers at professional meetings. See *id.* at 4–29.

The ALJ found credible Professor Doering’s testimony that controlled substances are “high alert drugs” and that among controlled substances, drugs such as “opioids, benzodiazepines, [and] other central nervous system depressant drugs” require “the highest level scrutiny” on the part of a pharmacist who is presented with prescriptions for these drugs. Tr. 692; ALJ at 28. Professor Doering testified that in pharmacy practice, there are various red flags, which create “a level of concern that might cause a pharmacist to either choose not to fill a prescription or take some other kind of actions,” and that “the more red flags there are, the stronger that suspicion is.” Tr. 694. Professor Doering testified that

while some red flags might be resolvable by checking a patient’s identification or calling the prescriber, there are also circumstances in which calling the prescriber will not resolve the red flags because the red flags indicate that the prescriber is collaborating with the patient to divert drugs. *Id.* at 697–700.

Professor Doering specifically identified such red flags as including that the patient is paying for controlled substance prescriptions with cash, *id.* at 703; the respective locations of the patient and the prescriber, *id.* at 701–02; that a prescriber writes for certain combinations or patterns of drugs, *id.* at 708; and multiple patients presenting “prescriptions for the same drugs, the same quantities * * * from the same doctor without any kind of variability or change considering the different patients that come into the pharmacy,” thus suggesting that the physician prescribes in a “factory like manner.” *Id.*

Professor Doering reviewed the various spreadsheets of the prescriptions dispensed by Respondents and testified regarding whether Respondents could have lawfully dispensed various prescriptions given the red flags they presented. For example, when questioned about Respondent CVS #219’s dispensing of oxycodone 30 mg prescriptions,⁸ which were issued by a Fort Lauderdale-based physician (P.G.) for persons whose addresses were in Kentucky and Tennessee and who paid cash, Professor Doering opined that the multiple red flags these prescriptions presented could not be resolved so that a reasonable pharmacist could dispense them consistent with his corresponding responsibility under federal law.⁹ Tr. 722–23.

⁸ Professor Doering acknowledged that “the doses of these medications (oxycodone 30 mg) are within therapeutic guidelines or limits, but, number one, it’s just extremely suspicious to me that these are always 30 milligram tablets, always in large quantities. * * * [P]eople come in all shapes, sizes and degrees of infirmity, and it just is an attention getter when I see the same drugs from the same doctors from similar places coming through in a nonstop sort of way.” Tr. 776.

⁹ The specific prescriptions were either for 180 or 210 tablets of oxycodone 30 mg. The evidence showed that on August 13, 2010, Respondent CVS #219 dispensed such prescriptions to a resident of Harrogate, Tennessee and a resident of Ingram, Kentucky; that on August 16, 2010, Respondent CVS #219 dispensed such prescriptions to another resident of Harrogate, Tennessee, as well as three residents of Middlesboro, Kentucky (one of whom received 56 tablets of OxyContin 80 mg), and a resident of Dayhoit, Kentucky; and that on September 24, 2010, it dispensed more oxycodone 30 mg prescriptions to three Kentucky residents, including two who had the same last name and town of residence (Middlesboro), as well as three residents of Tennessee. See GX 57, at 33. Each of these persons paid cash. *Id.*

As the ALJ found, the Government elicited additional testimony from its Expert regarding the prescriptions issued by other doctors which was to similar effect. For example, the Government noted that on August 29 and 30, 2010, Respondent CVS #219 filled prescriptions for either 210 or 240 tablets of oxycodone 30 mg for four Kentucky residents, all of whom paid cash, which were issued by a physician (L.A.) whose office address was listed as either in Miami or Fort Lauderdale. GX 57, at 15. Two of these individuals were from Clay City; the other two were from Stanton. *Id.*

Regarding these prescriptions, Professor Doering testified that he could not “foresee any explanation for this set of red flags that would satisfy my professional obligation not to fill the scripts.” Tr. 754. When further questioned as to whether anything “could have been done to resolve the[] red flags” presented by these prescriptions, Professor Doering explained that “it’s a conflagration or a combination of things that suggests to me that these prescriptions were not issued in the usual course of medical practice” and that nothing on the hard copy of the prescriptions “would change [his] opinion.” *Id.* at 757–58. And when asked by the ALJ if he was imposing a more stringent standard than the standard of a Florida pharmacist, Professor Doering testified that the standard he applied was “what they’re taught in school,” and that in his “many conversations with similar pharmacies operating under similar circumstances * * * the feedback I get is universally consistent with my point of view.” *Id.* at 758.

The Government also noted that on August 19, 2010, Respondent CVS #219 filled four prescriptions for 180 tablets of oxycodone 30 mg for four Kentucky residents, which were issued by a physician (C.N.) whose address was listed as either being in Delray Beach or Deerfield Beach, two cities located in Palm Beach County. Tr. 759–64; GX 57, at 38. Here again, Professor Doering testified that the red flags could not be resolved and that no information on the hard copy of the prescriptions would lead him to change his opinion. Tr. 764.

Professor Doering likewise testified regarding dispensings that occurred at Respondent CVS #5195. More specifically, he addressed Respondent’s dispensings on August 26, 2010, of several prescriptions for 180 tablets of oxycodone 30 mg written by a Dr. Jack

Danton¹⁰ of Pompano Beach for three residents of Tennessee, two of whom shared the same last name and address in Knoxville, with the other being from the town of Mascot. GX 57, at 29. Professor Doering testified that the red flags associated with these prescriptions included that they were paid for with cash, the prescriptions were for “a high alert drug,” that the patients were “from out-of-state who apparently traveled a great distance to be seen in Pompano Beach,” and that the assigned prescription numbers were very close sequentially, suggesting that it was “most likely they were presented to the pharmacy within a very short time span.” Tr. 751.¹¹ While Professor Doering was not specifically asked whether the combination of red flags presented by the Danton prescriptions was resolvable, based on his earlier testimony that other prescriptions, which were issued for the same drug and in similar quantities to persons who had travelled from out-of-state to South Florida to obtain the prescriptions and then on to Sanford to fill them presented red flags which were not resolvable, I conclude that the red flags presented by these prescriptions were also not resolvable.

Professor Doering further testified regarding Respondent CVS #5195’s dispensings on August 11, 2010 of six oxycodone 30 mg prescriptions (all but one of which were for 180 tablets¹²), issued by a Dr. Carlos Gonzales of West Palm Beach to six Kentucky residents, all of whom paid cash.¹³ GX 57, at 35. The evidence further showed that three of these persons lived in the same town

(Stanton) and that two of them had the same last name and street address; another two were also from the same town (Danville). *Id.* When asked whether a reasonable and prudent pharmacist in Sanford would want to resolve the red flags presented by these prescriptions before dispensing them, Professor Doering answered: “If it’s resolvable. I think I’ve testified already that there’s no explanation that’s going to resolve that in my mind.” Tr. 916.¹⁴

The Government also introduced an eighty-one page spreadsheet of the controlled substance prescriptions which were written by a Longwood, Florida physician and filled by both Respondents.¹⁵ The spreadsheet documents numerous instances in which both Respondents filled two or more controlled substance prescriptions that the physician typically wrote for 168 tablets of oxycodone 30 mg and 56 tablets of alprazolam 2 mg; moreover, in many instances, the patients received a third prescription for 56 tablets of oxycodone 15 mg. *See* GX 55.

The Government then asked Professor Doering for his opinion regarding the red flags that were presented by this doctor’s prescriptions and directed his attention to several prescriptions that each Respondent filled on December 23, 2010. More specifically, the Government noted the prescriptions that Respondent CVS #219 filled for patients T.F. and A.T., each of whom received 168 tablets of oxycodone 30 mg, 56 tablets of oxycodone 15 mg, and 56 tablets of alprazolam 2 mg; *see* GX 55, at 15, 47; as well as the prescriptions that Respondent CVS #5195 filled for patients C.H. and J.R., each of whom also received 168 tablets of oxycodone 30 mg, 56 tablets of oxycodone 15 mg, and 56 tablets of alprazolam 2 mg. *See id.* at 62, 74.¹⁶

¹⁴ Professor Doering further testified that “Interstate 95 has been renamed the Oxycodone Express because of the brisk travel of people from Kentucky, Tennessee, [and] Ohio to South Florida to obtain medications.” Tr. 775. He also testified with respect to these dispensings that:

Well, once again this is a clinic that’s at a distant site from someone living in Kentucky, and I don’t think it’s any secret that—I haven’t used the term yet, I won’t use the term—I’ll call them pain management clinics that are known to be—what should I say—fairly easy to get controlled substance prescriptions from.

Id.

¹⁵ The spreadsheet was provided by CVS to a DEA Group Supervisor, who then provided it to an Agency Investigator. Tr. 485. While the Investigator subsequently removed the title of the original document, she did not change the substantive information. *Id.*

¹⁶ Nor were these the only patients who, on the same date, filled at Respondents, prescriptions for the same combination of drugs which they obtained from this physician. *See* Tr. 787–91 (discussing patients B.D., A.H., R.M., J.W., each of whom, on

Regarding these prescriptions, Professor Doering Expert testified that from the perspective of “a clinical pharmacist * * * that combination of drugs is * * * a red flag because [a]lprazolam and oxycodone are commonly diverted to nonmedical use.” Tr. 784. As for the two oxycodone prescriptions each person obtained, Professor Doering explained that while “one might speculate that the reason for that is that pain can vary throughout the day and it may be that the individual is suggested to take the 15 [mg tablets] when the pain is not so great and 30 [mg tablets] when it is so great,” the “30 milligram tablets are scored right down the middle, and it’s quite easy to break them in half.” *Id.* Professor Doering thus explained that prescribing both fifteen and thirty milligram strengths of the drug “just doesn’t make any sense.” *Id.* He also testified that pill cutters are widely available in pharmacies and that it is common for doctors to prescribe a stronger strength of a drug to save money and instruct their patients to cut the drug in half. *Id.* at 786.

Professor Doering further testified that the prescribing patterns of this physician “would suggest that the one size fits all concept was in the” physician’s mind, and that this was “highly suspicious” because “you see the same drugs, the same quantities, the same patterns over and over again.” *Id.* at 784–85. Indeed, while the Government questioned Professor Doering about only a few of the prescriptions, the eighty-plus page spreadsheet manifests that this physician repeatedly engaged in the pattern prescribing of oxycodone with alprazolam and frequently provided these persons with prescriptions for both oxycodone 30 mg and 15 mg.¹⁷ Moreover, this was not the only physician who engaged in the pattern prescribing of oxycodone and alprazolam and whose prescriptions

January 6, 2011, filled prescriptions at CVS #219 for 168 tablets of oxycodone 30 mg, 56 tablets of oxycodone 15 mg, and 56 tablets of alprazolam 2 mg).

¹⁷ To counter the testimony of the Government’s Expert, Respondent called one of their own, Professor Brushwood, who is also a member of the faculty at the University of Florida College of Pharmacy. The ALJ carefully reviewed Professor Brushwood’s testimony and thoroughly explained why he did not find his testimony to be more persuasive than that of Professor Doering on the material issues of whether certain red flags presented by the prescriptions were unresolvable and whether Respondents’ pharmacists dispensed controlled substance prescriptions when they had reason to know that the prescriptions lacked a legitimate medical purpose and were not issued in the usual course of professional practice. *See* ALJ at 42. Having reviewed the record and the ALJ’s reasoning, I agree with the ALJ’s discussion of the weight he gave the testimony of each party’s expert.

¹⁰ Dr. Danton’s registration was subsequently revoked by the Agency following a hearing. *See Jack A. Danton*, 76 FR 60,900, 60,922 (2011).

¹¹ While the spreadsheet indicates that the prescriptions were subject to a “cash discount,” which apparently means that the patients were entitled to some type of group discount, I adopt the ALJ’s finding that even if this red flag is eliminated from the factors which a pharmacist must consider, “the remaining red flags [we]re still unresolvable.” ALJ at 30–31 n.54. So too, I adopt the ALJ’s findings that while Professor Doering conceded that he did not know at what point the prescription numbers were assigned, the prescriptions at issue “were presented in proximity to one another.” *See id.* at 31 n.55 (quoting Tr. 926–27).

¹² The other prescription was for 150 tablets. GX 57, at 35.

¹³ Respondents argue that the ALJ improperly relied on three of the six controlled substance prescriptions that were issued by Dr. Gonzales and dispensed by Respondent CVS #5195 on August 11, 2010, because Professor Doering did not specifically address all six of them in his testimony. Resp. Exceptions, at 27. However, having identified those circumstances presenting red flags, which according Professor Doering could not be resolved, the ALJ could reasonably apply this testimony in assessing the lawfulness of Respondents’ dispensings of other prescriptions that presented similar unresolvable red flags.

were filled by Respondents. *See, e.g.*, GX 35.

Respondents take exception to the ALJ's reliance on Professor Doering's testimony. Resp. Exceptions, at 18–22. More specifically, they assert that Professor Doering's testimony is unreliable because he did not use a reliable methodology in formulating his opinions. *Id.* at 18–21. They also assert that Professor Doering's testimony is biased because he acknowledged having testified for the Government in “virtually all” of the cases in which he has testified as an expert. *Id.* at 21–22.

As for the claim of bias, Respondents' argument provides no reason to reject the ALJ's credibility determination. The mere fact that Professor Doering has consistently testified for the Government is not sufficient to prove bias.

As for the claim that Professor Doering's testimony was unreliable, Respondents contend this is so because he “spent insufficient time reviewing the dispensing data,” “failed to review (or to request) any hard-copy prescriptions,” “relied on data pre-selected by the Government instead of conducting an independent evaluation of all of the data available,” and that he “fundamentally misunderstood the data he reviewed.” Resp. Exceptions, at 20. Respondents' contentions are not persuasive.

As for the first assertion, Respondents note that “Professor Doering spent fewer than ten hours reviewing” the dispensing data. *Id.* at n.9. However, Respondents offer no explanation as to why this was insufficient to review the data.

With respect to the second assertion, given that much of Professor Doering's testimony centered on certain prescriptions that presented a collection of red flags that no reasonable and prudent pharmacist could resolve so as to lawfully fill the prescriptions, his failure to review the hard-copy prescriptions is of no consequence. As Professor Doering testified with respect to several of the prescriptions, the fact that he was not provided with the hard copy prescriptions did not affect his opinion because “[t]here's nothing that I could gain from that review that would change my opinion.” Tr. 758.

As for Respondents' claim that Professor Doering relied on data which was pre-selected by the Government rather than conduct an independent evaluation of all of the available data, Respondents cite to his testimony that the Government provided him with a spreadsheet that listed the cash-only transactions. Resp. Exceptions, at 20 n.11 (citing Tr. 849:8–852:18).

Respondents' counsel then asked Professor Doering whether “when the Government provided that information to [him] they also consider[ed] cash discount to be the same thing as cash?” Tr. 851. Professor Doering answered that he could not “remember” and added that he did not do anything to look at the individual prescriptions and determine which ones were actually paid for with cash.¹⁸ *Id.*

Respondents' argument gains no traction because Professor Doering subsequently explained that even if a patient presented a card entitling him to a cash discount, this would not address the other red flags which may have been present. Tr. 924. As Professor Doering further testified, “you have to look at it in totality of the issues that give you reason for concern.” *Id.* at 924–25. And with respect to the prescriptions that he discussed during his direct examination, Professor Doering explained that even after eliminating the red flag of cash payments, there were still other red flags present which could not have been resolved so as to lawfully dispense the prescriptions.¹⁹ *Id.* at 925.

Thus, contrary to Respondents' contention, Professor Doering's testimony, coupled with the evidence he reviewed, is more than enough to satisfy the Government's burden of proof. Moreover, the Government elicited additional testimony that, while it did not address any specific prescriptions, provides further support for the conclusion that Respondents' pharmacists repeatedly dispensed prescriptions when they had reason to know that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice. 21 CFR 1306.04(a).

More specifically, on October 18, 2011, DEA Investigators served Administrative Inspection Warrants at both Respondents and interviewed various employees of each store's pharmacy departments including their pharmacists-in-charge. At CVS #5195, a DEA Investigator (DI) interviewed Ms.

¹⁸ The evidence showed that the term “Cash Discount” referred to those transactions in which a patient presented a discount card such as from the AARP. It is not clear why a person's presentation of such a card would make the transaction any less suspicious if other red flags were present.

¹⁹ Respondents also note that Professor Doering acknowledged on cross-examination that he did not know how CVS assigns prescription numbers. Resp. Exceptions, at 20 & n.12. However, this does not provide reason to reject his testimony, because there were ample other red flags presented by the prescriptions, especially by those which were presented by persons who gave out-of-state addresses as their residences and yet had obtained their prescriptions from a doctor located in South Florida.

Jessica Merrill, its pharmacist-in-charge. Tr. 227. Ms. Merrill stated that “she could fill oxycodone * * * prescriptions all day long, but rather than doing that, she had decided to set a limit * * * each morning” on the number of prescriptions the store would fill for oxycodone (as well as alprazolam), which was based on the available inventory of oxycodone and the amount of staff on hand. *Id.* at 229–30. Ms. Merrill stated that “once the limit [was] reached,” customers who then presented oxycodone prescriptions were told the store was out-of-stock even when it still had stock on hand.²⁰ *Id.* at 230. Ms. Merrill further stated that “the limit [was] basically based upon a first-come, first-served system” and that as a result, “customers would start staggering in at 8:02 a.m. to present their prescriptions.” *Id.* at 230–31.

When asked by the DI why she was limiting the number of prescriptions the store would fill as the store still had oxycodone in inventory, Ms. Merrill replied that “she had to keep a certain amount of oxycodone on hand to fill prescriptions * * * for her real pain patients.” *Id.* at 231–32. According to the DI, she then asked Ms. Merrill why she would fill prescriptions “from these not-real pain patients.” *Id.* at 233–34. Ms. Merrill replied that “as a pharmacist she was stuck between a rock and a hard place, and that basically * * * she had not been trained to diagnose,” and that if she or her staff were “able to confirm that a prescription had been issued by a physician who was licensed by the state, and had a DEA license, then . . . [the pharmacy] should be able to trust that that prescription—or that physician is legitimate, and that the doctor * * * ha[d] given the correct diagnosis.” *Id.* at 234.

Ms. Merrill further acknowledged that patients were presenting patterns of prescriptions that included oxycodone, an anti-anxiety medication, and a muscle relaxant; she also admitted that “a lot of these customers were paying for their prescriptions in cash.” *Id.* at 238. When questioned by the DI as to why the patients were using cash

²⁰ At approximately 10:30 a.m. on the day the IAW was served, the DI encountered a person in a massage chair, who related that he had come to the store to fill an oxycodone prescription only to be told by a pharmacy technician that the pharmacy was out of stock. Tr. 221. However, because the Investigators had counted the stock of oxycodone, the DI knew this was not true. *Id.* at 222–23. Upon asking the pharmacy technician why she had told the person this, the technician explained that the store placed a limit each morning on the number of oxycodone prescriptions it would fill that day. *Id.* at 223–24.

instead of insurance, Ms. Merrill stated “most of them are unemployed.” *Id.* When the DI then asked how the patients could afford to pay for hundreds of dollars-worth of prescriptions if they were unemployed, Ms. Merrill stated that she did not know. *Id.* However, when the DI suggested that the patients might be selling their pills, Ms. Merrill said: “I know.” *Id.*

The DI further testified that she had obtained the prescriptions that the pharmacy had accepted for filling that day, *id.* at 226, and that upon reviewing them, observed that “[t]he prescriptions from one particular physician’s office basically appeared to be all for the same quantity and the same combination of drugs.” *Id.* at 239. However, when she discussed this with Ms. Merrill, the latter “basically stated that * * * as a pharmacist, she is not trained to diagnose, and it’s up to the doctor to determine whether or not they need a prescription.” *Id.*

The DI also observed that some of the prescriptions were issued by a physician located near or in Orlando for a patient from Daytona Beach. *Id.* at 240. The DI then asked Ms. Merrill whether she found it “a little odd” that the patients had presented their prescriptions in Sanford,²¹ given that there are CVSs all over central Florida and that the patients “obviously passed multiple CVSs coming from the doctor.” *Id.* Ms. Merrill, however, did not “know why they did that.” *Id.*

On October 28, 2011, the DI also participated in an interview of other employees of the Respondents at the local DEA field office, including Mr. Paras Priyadarshi, the pharmacist-in-charge at Respondent CVS #219. *Id.* at 244–45. According to the DI, the prescription records for CVS #219 showed that it was “basically filling prescriptions for the same type of cocktail prescribing pattern that CVS #5195 had been dispensing,” namely combinations of oxycodone, alprazolam, and carisoprodol.²² *Id.* at 247. When

asked whether he found it “odd that all of these practitioners in the area” that the pharmacy was “filling for,” were writing prescriptions for the same combination of drugs “to all these different patients,” Mr. Priyadarshi answered that he did not find it odd and that this was the combination of drugs these doctors prescribed. *Id.* at 248. Nor did Mr. Priyadarshi find it odd that when “prescriptions came from a specific doctor, every single patient had the same ailment.”²³ *Id.* at 250. And when asked whether the patients asked for a certain brand of drugs, Mr. Priyadarshi stated that the patients “would come in and ask for the ‘Ms’ or the ‘blues,’” which are street slang references to the thirty milligram oxycodone tablets manufactured by Mallinckrodt. *Id.*; see also *id.* at 254 (testimony regarding statements of Susan Masso, another pharmacist who worked at Store #219). However, Mr. Priyadarshi did not find it suspicious that patients would use street slang to ask for thirty milligram oxycodone.²⁴ *Id.* at 256, 264.

The statements of Respondents’ employees thus manifest a complete abdication of their responsibility “to exercise professional judgment” before dispensing prescriptions for highly abused controlled substances. *Ralph J. Bertolino, d/b/a/Ralph J. Bertolino Pharmacy*, 55 FR 4,729, 4,730 (1990). This evidence provides further support for the conclusions that each

which includes oxycodone and alprazolam. See *East Main Street Pharmacy*, 75 FR 66,149, 66,158 (2010) (noting expert’s testimony that “[i]t is well known in the pharmacy profession [that] the combination of a benzodiazepine, narcotic pain killer, and Soma [the branded version of carisoprodol] [is] being used by patients abusing prescriptions drugs”); *Paul J. Volkman*, 73 FR 30,630, 30,637–38 (2008) (discussing expert’s testimony regarding abuse of drug cocktails of oxycodone, alprazolam, and carisoprodol).

²³ On direct examination, the DI did not identify the specific doctor she was referring to. However, on cross-examination, the DI identified by name a Longwood, Florida physician who “writes the same prescriptions, the same combinations of drugs, to all of his patients.” Tr. 274. This is the same physician whose prescriptions are listed in the eighty-one page spreadsheet which is GX 55.

The DI further noted that while this physician “may vary the quantity” of oxycodone from patient to patient, “the majority of the prescriptions are for the combination of oxycodone, alprazolam, and carisoprodol or Soma.” *Id.* The record also contains a number of oxycodone prescriptions which were written by this physician, most of which contain the same DX Code. See GX 67 (of nine prescriptions issued by physician on April 26, 2011, eight list DX code of 724.2); GX 68 (of eighteen prescriptions issued by physician on May 19, 2011, sixteen list DX Code of 724.2).

²⁴ Here too, the ALJ found the testimony of the Agency’s Investigators regarding the statements made by these employees to be credible. See ALJ at 24, 66–68. And while the statements are hearsay, they are inherently reliable as statements against interest. Cf. Fed. R. Evid. R. 804(b)(3).

Respondent dispensed numerous prescriptions when their pharmacists either knew or had reason to know that the prescriptions lacked a legitimate medical purpose and were issued outside of the usual course of professional practice and thus violated the CSA. See 21 CFR 1306.04(a).

Respondents nonetheless contend that the ALJ improperly shifted the burden of proof from the Government to them. Resp. Exceptions, 15–18. More specifically, Respondents note that in a pre-hearing order, the ALJ held that to prove a violation of 21 CFR 1306.04(a), the Government was required to prove the following elements: (1) That “the Respondent dispensed a controlled substance”; (2) that “a red flag was or should have been recognized at or before the time the controlled substances was dispensed”; and (3) that “the red flag was not resolved conclusively prior to the dispensing of the controlled substance.” ALJ Ex. 28, at 11–12; see also Resp. Exceptions, at 15–16.

Respondents argue that the ALJ improperly required them “to present evidence that the red flags discussed by the Government were, in fact, resolved, in lieu of holding the Government to its obligation to prove that these red flags were not resolved.” Resp. Exceptions, at 16 (emphasis in original). According to Respondents, the Government “did not identify any of these prescriptions, which it selected for Professor Doering from a pool of 25,000, until Professor Doering testified at the hearing.” *Id.* Respondents note that the Government did not introduce the hard-copy prescriptions and that its case “relied on an analysis of spreadsheets of Respondents’ dispensing data and its expert’s conclusory assertion that all the red flags on the prescriptions [which] he identified from the spreadsheets were simply ‘unresolvable.’” *Id.* at 17. Respondents thus contend that the Government “failed to meet the burden of proof to demonstrate that the identified red flags were or were not resolved” and that the ALJ improperly shifted the burden of production to them. *Id.*

As discussed above, with respect to multiple prescriptions, particularly those which were presented by non-Florida residents, who had obtained the prescriptions from doctors in South Florida located more than 200 miles from Respondents, and yet filled them at Respondents, the ALJ found credible Professor Doering’s testimony that the red flags were not resolvable and that nothing on the particular prescription (such as a notation by the pharmacist of having verified the prescription or the

²¹ The DI testified that the distance between Orlando and Sanford was “a little less” than 30 miles. She further testified that in her experience patients fill their prescription at pharmacies located either near their doctor’s office or near their residence.

²² At the time of the interview carisoprodol was not a controlled substance under federal law. On December 12, 2011, DEA issued a final rule placing carisoprodol in schedule IV of the Controlled Substances Act, effective January 11, 2012. See *Schedules of Controlled Substances: Placement of Carisoprodol Into Schedule IV*, 76 FR 77,330 (2011). However, during the relevant period, carisoprodol was a controlled substance under Florida law. See Fla. Stat. § 893.03(4)(jjj) (2010). Moreover, several Agency decisions had discussed the abuse of carisoprodol when taken as part of a drug cocktail

diagnosis) would lead him to change his conclusion. While the ALJ's pre-hearing order did not explicitly contemplate the scenario that certain red flags could not be resolved conclusively so as to permit a lawful dispensing, it is clear that if the red flags presented by a prescription could not be resolved, then the Government satisfied the third element of its *prima facie* burden. The ALJ thus did not improperly shift the burden of proof to Respondents.²⁵ Accordingly, I reject the contention.²⁶

While not discussed in their brief under this exception, Respondents raise several other arguments, which are closely related to their main contention that the Government has not shown that they violated 21 CFR 1306.04(a). First, with respect to the dispensings that occurred in 2010, they argue that "the Government failed to establish that the red flag would have been known to a reasonable pharmacist *at the time the prescription was presented*." Resp. Exceptions, at 27. Respondents further argue that "pharmacists and pharmacies in Florida were just beginning to see significant increases in prescriptions for oxycodone and to experience the effects of Florida's pill mill legislation." *Id.* Respondents thus contend that there is no evidence "that any of the alleged red flags of diversion about which Professor Doering testified would or should have

been recognized as red flags during the early stage of the oxycodone epidemic." *Id.*

As discussed by an Agency Investigator, the Florida pill mill crisis was "no secret," Tr. 43, and was the subject of "a lot of publicity in the press." *Id.* at 52. Thus, in response to the societal harms²⁷ caused by the diversion and abuse of prescription drugs including oxycodone and alprazolam, in 2010, the Florida legislature enacted legislation which, *inter alia*, restricted the amount of schedule II narcotics, such as oxycodone, which a prescriber could dispense directly to a patient who paid for the medication with cash, check, or credit card, to no more than a 72-hour supply. Tr. 44–45; see Fla. Stat. Ann. § 465.0276(1)(b)(2011). As a consequence of the law, for those patients who lacked a third-party payer, prescribers were required to write paper prescriptions, which a patient was required to fill at a pharmacy. *Id.*

Respondents and their supervisory management cannot reasonably claim ignorance of the Florida pill mill problem or the legislation enacted by the State. Likewise, Respondents' protestation of ignorance begs the question of what they expected would occur upon the enactment of the State's pill mill legislation.

In any event, even before many of the dispensings which are at issue here, this Agency had published several decisions which discussed the diversion and abuse of oxycodone, as well as drug cocktails which included oxycodone, alprazolam, and carisoprodol. See *Paul J. Volkman*, 73 FR 30,630 (2008) (discussing drug cocktails issued by physician for oxycodone, benzodiazepines and carisoprodol, expert testimony of abuse potential of these drugs, and red flag of patient travelling long distance to fill prescriptions); see also *East Main Street Pharmacy*, 75 FR 66,149 (Oct. 27, 2010) (discussing abuse of oxycodone, alprazolam, and carisoprodol and red flag of patients traveling long distances to fill prescriptions); *Your Druggist Pharmacy*, 73 FR 75,774, 75,775 n.1. (2008) (noting that "[w]hile carisoprodol [was] not controlled under Federal law, it is controlled under various state laws and is highly popular with drug abusers, especially when taken as part of a drug cocktail that includes an opiate and a benzodiazepine"). Beyond this, the red

flags presented by the circumstances of patients travelling from Kentucky or Tennessee to South Florida to obtain prescriptions, including for a schedule II narcotic, which by definition has the highest potential for abuse of any drug that may be prescribed lawfully, see 21 U.S.C. 812(b)(2), and then travelling to Respondents to fill them, are so obvious that only those who are deliberately ignorant would fill these prescriptions. I thus reject this contention as well.

I therefore conclude that the ALJ's finding that both Respondents repeatedly dispensed controlled substances in violation of 21 CFR 1306.04(a) is supported by substantial evidence.²⁸ ALJ at 69–70. I further adopt the ALJ's finding that "the Government has established that the Respondents have committed acts that are inconsistent with the public interest" and that "the record evidence under the Fourth and Second Factors weighs in favor of revocation." *Id.*

Exception Three—The ALJ Failed To Consider Evidence of Respondents' Acceptance of Responsibility

Respondents also argue that the ALJ erred in holding that "they 'have not accepted responsibility for the actions

²⁵ As discussed above, the Government did introduce the prescriptions issued by the Longwood, Florida physician which were filled on two separate dates. While these prescriptions contained a diagnosis code, and nearly all of the prescriptions on each date contained the same code, it is not clear who wrote the code on the prescription. However, even if Respondents' pharmacists or pharmacy technicians had called the physician, the dispensing pharmacists clearly were aware that this prescriber was prescribing the same combination of controlled substances to nearly all of his patients and nearly all of the patients had the same diagnosis. The pharmacists thus clearly had reason to know that these prescriptions were unlawful and chose to ignore that information.

²⁶ Respondents also contend that there is no legal authority to support the Expert's testimony "that certain red flags are unresolvable on their face." Resp. Exceptions, at 9–10. Contrary to Respondents' contention, for more than thirty years (if not longer), it has been settled law that a pharmacist can be held liable for violating 21 CFR 1306.04(a) even if he calls the prescriber and verifies the prescription. See, e.g., *East Main St. Pharmacy*, 75 FR 66,149, 66,164 (2010) (quoting *United States v. Hayes*, 595 F.2d 258, 261 (5th Cir. 1979)). As the Fifth Circuit explained in *Hayes*, "[v]erification by the issuing practitioner on request of the pharmacist is evidence that the pharmacist lacks knowledge that the prescription was issued outside the scope of professional practice. But it is not an insurance policy against a fact finder's concluding that the pharmacist had the requisite knowledge despite a purported but false verification." 595 F.2d at 261. See also *United States v. Seelig*, 622 F.2d 207, 213 (6th Cir. 1980) (upholding jury instruction that knowledge may be inferred from evidence that pharmacists "deliberately closed their eyes to what would otherwise be obvious to them"); see also *Bertolino*, 55 FR at 4,730.

²⁷ Among the harms identified by the DI identified were an increase of 345 percent in oxycodone overdose deaths between 2005 and 2010, and an increase, during the same time period, in the number of babies born who were addicted to oxycodone from 258 to 1,374 per year. Tr. 44.

²⁸ Respondents also take exception to the ALJ's exclusion of testimony of their proposed pain management experts. Resp. Exceptions, at 36–37. Respondents assert that they have been prejudiced by the ALJ's ruling, and that their experts would have provided testimony to the effect "that certain quantities and combinations [of controlled substances] would not be considered 'large' or 'unusual' for the treatment of pain" and that "[i]t is difficult to see how such practices could-or should-raise a suspicion regarding the validity of a prescription," when qualified experts on the "usual course of professional practice in the relevant field would testify that there is nothing suspicious about what was prescribed." Resp. Mot. for Reconsideration, at 4 (ALJ Ex. 30) (quoting Order on Hearing Scope and Government Motion Regarding the Respondents' Experts at 11) (ALJ Ex. 28).

In support of their motion, Respondents proffered the reports of two pain management physicians. See Resp. Mot. to File Expert Reports (ALJ Ex. 25). Yet in their reports, neither physician specifically addressed whether the prescriptions for the combination of controlled substances (*i.e.*, oxycodone and alprazolam) filled by Respondents were issued for a legitimate medical purpose. Moreover, even Professor Brushwood acknowledged that while prescriptions for this combination of controlled substances could be prescribed for legitimate medical purposes, "it is also sought after by people who would divert and abuse drugs." Tr. 1082. He also testified that both drugs present a high risk for abuse or diversion and also agreed that a pharmacist must be "particularly conscious of potential diversion issues" when dispensing these drugs. *Id.* at 1086.

Accordingly, even assuming that there are patients to whom a physician can legitimately prescribe these controlled substances simultaneously, as the Government's Expert testified, it is the totality of the red flags which renders them unresolvable and thus made the dispensings unlawful.

that form the basis of the Government's *prima facie* case." Resp. Exceptions, at 22 (quoting ALJ at 72). According to Respondents, the ALJ failed to "credit the unequivocal statements of CVS's Vice President of Pharmacy Operations explaining that CVS accepted responsibility on behalf of Respondents and fails entirely to consider the significant evidence of the swift and targeted actions taken by CVS in the wake of the [Administrative Inspection] Warrants to address and resolve the precise concerns identified by DEA at Stores 219 and 5195." *Id.* at 23. They further contend that "CVS's actions speak volumes to its acceptance of responsibility for Respondents' dispensing practices and for assuring that its pharmacies and employees meet their legal obligations." *Id.* However, having reviewed the record, I agree with the ALJ's conclusion that "Respondents have not accepted responsibility for the actions that form the basis of the Government's *prima facie* case." ALJ at 72.

This Agency has repeatedly held that where the Government has proved that a registrant has committed acts inconsistent with the public interest, a registrant must "present[] sufficient mitigating evidence to assure the Administrator that [it] can be entrusted with the responsibility carried by such a registration." *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008) (quoting *Samuel S. Jackson*, 72 FR 23,848, 23,853 (2007) (quoting *Leo R. Miller*, 53 FR 21,931, 21,932 (1988))). Moreover, because "past performance is the best predictor of future performance," *ALRA Labs., Inc., v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), this Agency has repeatedly held that where a registrant has committed acts inconsistent with the public interest, the registrant must both accept responsibility for its actions and demonstrate that it will not engage in future misconduct. *Medicine Shoppe-Jonesborough*, 73 FR at 387; see also *Jackson*, 72 FR at 23,853; *John H. Kennedy*, 71 FR 35,705, 35,709 (2006); *Prince George Daniels*, 60 FR 62,884, 62,887 (1995).

DEA cases make clear that admitting fault for past misconduct is an important factor in determining whether a registrant has rebutted the Government's *prima facie* showing that its continued registration would be "inconsistent with the public interest." 21 U.S.C. 824(a)(4). As the Tenth Circuit recently held in rejecting a physician's contention that the Agency exceeded its statutory authority in considering whether he had admitted fault for his prescribing violations:

The DEA may properly consider whether a physician admits fault in determining if the physician's registration should be revoked. When faced with evidence that a doctor has a history of distributing controlled substances unlawfully, it is reasonable for the . . . Administrator to consider whether that doctor will change his or her behavior in the future. And that consideration is vital to whether the continued registration is in the public interest. . . . [T]he . . . Administrator had no evidence that Dr. Mackay recognized the extent of his misconduct and was prepared to remedy his prescribing practices.

MacKay v. DEA, 664 F.3d 808, 820 (2011) (citing *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005)). See also *Chein v. DEA*, 533 F.3d 828, 837 (D.C. Cir. 2007) (upholding revocation order, noting in part that physician had not "accepted responsibility for his misconduct"); *Hoxie*, 419 F.3d at 483 (DEA properly considers admission of fault in determining whether a registration should be revoked).

As noted above, Respondents contend that the ALJ failed to give proper weight to what they characterize as "the unequivocal statements of CVS's Vice President of Pharmacy Operations explaining that CVS accepted responsibility on behalf of Respondents." Resp. Exceptions, at 23. However, at the hearing, the evidence offered to rebut the Government's *prima facie* case focused entirely on various measures CVS implemented following the execution of the Administrative Inspection Warrants in October 2011. Contrary to Respondents' assertion, the only testimony of the company's official that even mentioned the word "responsibility," occurred in response to the question posed by their counsel as to why CVS had taken various actions since October 2011. Tr. 1296. In response, the official testified:

CVS takes its responsibility seriously, and given the drug abuse, the elevated level of drug abuse, that's being observed broadly in Florida, we don't want to contribute to that, and to the extent that any of our stores could contribute to that, we wanted to take these steps to help ensure that no stores do in the future. We understand that it's our responsibility to provide our stores the tools and information that they need to do their jobs on a day-to-day basis and in compliance with state, federal and local legislation and requirements, and we felt these actions helped us do so.

Id. at 1296–97.

As the ALJ found, at no point did this official acknowledge that Respondents had engaged in any misconduct. Indeed, in their post-hearing brief, Respondents all but concede as much, arguing that the Agency "cannot point to another instance where a revocation of a chain pharmacy's license has occurred in

similar circumstances." Resp. Proposed Findings of Fact and Conclusions of Law (Post-Hearing Br.), at 123. Respondents further contend that "other DEA revocation cases bear a crucial distinction from this case: in virtually all of those cases, the individual doctor or independent pharmacy owner/pharmacist was both the one accused of wrongdoing and the registrant. As such, these individuals were in a position to apologize for their own misconduct or that of the retail pharmacy they owned or operated." *Id.*

Be that as it may, the Agency's rule is clear and the fact that CVS is a large corporation provides no reason to excuse it from explicitly acknowledging the misconduct of Respondents and their pharmacists. Therefore, I decline to create one rule for chain pharmacies and another rule for closely held or sole-proprietor owned pharmacies. Because Respondents have failed to satisfy this requirement, the ALJ properly held that they have not accepted responsibility for their misconduct.

Nor, even with respect to whether CVS has successfully demonstrated that it will not engage in future misconduct, is its evidence convincing. It is acknowledged that CVS made changes to its pharmacy software, issued new dispensing guidelines, and is requiring its pharmacy personnel to undergo additional training. However, other evidence still raises serious questions as to how seriously CVS takes its responsibility to comply with federal law.

For example, Respondents point to the fact that at the time of the Administrative Inspection Warrants, they became aware of the Government's concerns that they were dispensing oxycodone prescriptions issued by certain "high-volume prescribers" and ceased dispensing schedule II narcotic prescriptions issued by these physicians. *Id.* at 23–24; see also GX 29 (November 15, 2011 email from Respondent's counsel to DI noting that CVS would be suspending various physicians). Yet, among these physicians was the same Longwood, Florida physician, who repeatedly prescribed combinations of oxycodone and alprazolam based on nearly uniform diagnoses, which both Respondents repeatedly filled (and had been doing so for at least six months), notwithstanding that it was clear that he was engaged in pattern prescribing. See GX 55 (eighty-one page spreadsheet of each Respondent's dispensings of physician's prescriptions); GXs 67 & 68. Respondents offer no explanation for why they could not figure out on their

own that this physician was issuing unlawful prescriptions.²⁹

Respondents also argue that CVS has appointed new pharmacists-in-charge at each store. Resp. Post-Hearing Br. 126. According to Respondents, “[t]his employment decision was made ‘in the best interest of the stores’ and was designed to provide new leadership for the pharmacies.” *Id.*; see also Tr. 1294 (testimony of CVS Vice President; decision “was based on the additional scrutiny within the stores related to these hearings, the company felt it was in the best interest of those pharmacies to bring in new leadership that would not be distracted by these events”).³⁰ However, CVS’s Vice President did not know what further personnel actions were being taken with respect to these individuals. Tr. 1295. Given the egregiousness of their misconduct, it is stunning that CVS offered no assurance that these individuals had been discharged from employment. See 21 CFR 1301.92. Accordingly, I agree with the ALJ that Respondents have not rebutted the Governments’ *prima facie* case.³¹

²⁹ Indeed, in a December 2010 meeting, DEA Investigators explained to CVS officials various red flags to look for including the prescribing of the combination of oxycodone and alprazolam. Tr. 52. The DI further testified that “We brought up examples again of people coming in from the same doctors with the same prescriptions for Oxycodone, 15 milligrams, 30 milligrams[,] alprazolam, two milligrams, a lot of people wanting to pay cash, a lot of people wanting to drive distances to the pharmacy or to the doctor.” *Id.* at 55. In addition, the Investigators told CVS’s representatives that it was a red flag when “individuals * * * come in with the same prescriptions, also the same diagnosis.” *Id.* at 56. The Investigators also explained that calling a doctor to verify whether he wrote a prescription would not be sufficient to determine whether a prescription complied with federal law, and CVS’s representatives agreed. *Id.* at 57.

³⁰ The Vice President did not know when CVS had replaced the two pharmacists-in-charge and did not even know generally when it had occurred. Tr. 1294.

³¹ I have also considered Respondents’ various arguments regarding a proposed settlement of allegations based on CVS’s pharmacies having filled prescriptions issued by various prescribers who did not have current or valid DEA registrations. Suffice it to say, the settlement has not been agreed to by the Department of Justice. Moreover, even were I to consider the settlement as evidence of CVS’s acceptance of responsibility for filling the prescriptions issued by Dr. Lynch, the settlement does not address Respondents’ misconduct in dispensing numerous prescriptions in violation of 21 CFR 1306.04(a).

I have also considered the rest of Respondents’ exceptions and conclude that they are either without merit or fail to establish prejudicial error. Cf. 5 U.S.C. 706 (“due account shall be taken of the rule of prejudicial error”). For example, Respondents argue that the ALJ made a factual finding that at Store 5195, an Agency Investigator had observed a person who had dilated pupils and that this evidence was not admissible pursuant to the ALJ’s Scope Order. Resp. Exceptions, at 26. Be that as it may, the ALJ did not cite this testimony

Respondents further argue that the ALJ’s recommended sanction is overly broad and that any sanction should be limited to oxycodone or schedule II controlled substances. Resp. Exceptions, at 25–26. According to Respondents, this is so because “the Government’s evidence focused almost exclusively on Respondents’ dispensing of oxycodone” and “the only evidence regarding other controlled substances related to substances commonly dispensed in conjunction with oxycodone.” *Id.* at 25.

I acknowledge that DEA possesses the discretion to limit an order of revocation to a particular controlled substance. See 21 U.S.C. 824(b). However, I conclude that to exercise that discretion here would be particularly inappropriate and ill-serve the public interest.

The Agency has previously held that “[t]he Government is not required to prove that multiple categories of [controlled substances] were diverted in order to sustain the revocation of [a registrant’s] entire registration.” *Southwood Pharmaceuticals, Inc.*, 72 FR 36,487, 36,503 (2007). Rather, proof that a registrant has diverted any category of a controlled substance is sufficiently egregious misconduct to warrant the revocation of a registrant’s entire registration. See *id.* (rejecting ALJ’s recommendation to limit revocation to a single drug and revoking distributor’s registration based solely on evidence registrant diverted hydrocodone, a schedule III drug).

In any event, Respondents diverted not only schedule II drugs, which have been placed in this schedule because they have the highest potential for abuse and the abuse of them “may lead to severe psychological or physical dependence,” see 21 U.S.C. 812(b)(2), but also schedule IV benzodiazepines.³² Moreover, Respondents’ misconduct was both egregious and of extensive duration and undoubtedly caused extensive harm to the public interest, notwithstanding the assertion of CVS’s Vice President that CVS does not want to contribute to the prescription drug abuse problem. This is more than enough to conclude that the revocation of the entirety of each Respondents’ controlled substance dispensing authority is necessary to protect the

as support for his legal conclusions and thus Respondents cannot show prejudice. See also Resp. Exceptions, at 29 (arguing that ALJ inserted “irrelevant and prejudicial facts into his findings of fact” but not showing any prejudice).

³² Moreover, with respect to Dr. Lynch’s unlawful prescriptions, the evidence shows that Respondents’ dispensed controlled substances in schedules II, III, and IV. See GX 32, at 2 (alprazolam, schedule IV), 5 (zolpidem, schedule IV), 6 (OxyContin, schedule II), 9 (Endocet (oxycodone)), 10 (oxycodone).

public interest. I therefore reject Respondents’ contention that the ALJ’s recommendation is overly broad and adopt the ALJ’s recommended sanction.³³

Order

Pursuant to the authority vested in me by 21 U.S.C. 823(f) and 824(a)(4), as well as 28 CFR 0.100(b), I order that DEA Certificate of Registration Number BC5289055, issued to Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #00219, and DEA Certificate of Registration Number BC6988298, issued to Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #5195, be, and they hereby are, revoked. I further order that any pending applications of Holiday C.V.S., L.L.C., d/b/a CVS Pharmacy #00219 or #5195, be, and they hereby are, denied. This Order is effective November 13, 2012.

Dated: August 31, 2012.

Michele M. Leonhart,
Administrator.

*Paul Soeffing, Esq., Jason Hedges, Esq.,
Christine Menendez, Esq., for the
Government*

³³ The Government takes exception to the ALJ’s exclusion of evidence showing the oxycodone purchases of each Respondent. Gov. Exceptions, at 1. The Government contends that “[s]urely these figures would have (and, in fact, should have) caused someone at CVS #219 and CVS #5195 to inquire as to why their stores . . . were purchasing increasingly large quantities of oxycodone in order to fill the huge volume of oxycodone prescriptions being presented by their customers.” *Id.* at 2–3. The Government further asserts that “the volume of oxycodone purchased by CVS #219 and CVS #5195 eclipsed the amount of oxycodone purchased by other stores located in more densely populated cities within the State of Florida.” *Id.* at 3.

The rejected exhibits are, however, simply a compilation of the purchases of the Respondents. The Government made no proffer that it had performed a statistically valid study of the oxycodone purchases by CVS pharmacies (as well as other pharmacies) in the State of Florida, or even within the central Florida area, and that even after controlling for the relevant variables which might legitimately affect purchasing patterns, the Respondents’ increased purchases could not be explained by an increase in legitimate prescriptions. Nor is it clear what the evidence adds as the testimony establishes that following the enactment of the 2010 Florida pill mill bill, CVS’s officials requested a meeting with DEA because “they had seen an increase in the numbers of prescriptions for oxycodone,” and at the meeting, the purchases of both Respondents were specifically discussed. Tr. 52, 58, 80–81. Thus, there is ample evidence that CVS officials were on notice that something was amiss at both pharmacies.

Finally, as the ALJ properly held, Respondents’ purchases do not establish a violation of 21 CFR 1306.04(a). Rather, such a violation must be established by reference to a specific prescription and evidence indicating that Respondents’ pharmacists dispensed the prescription notwithstanding that they either knew or had reason to know that the prescription lacked a legitimate medical and was issued outside of the usual course of professional practice. See Order on Hearing Scope, at 7–12 (ALJ Ex. 28). I thus reject the Government’s contention.

Catherine O'Neil, Esq., John A. Gilbert, Esq.,
Colleen P. Schoch, Esq., Karla L. Palmer,
Esq., Barbara Rowland, Esq., for the
Respondents

RECOMMENDED RULINGS, FINDINGS OF
FACT, CONCLUSIONS OF LAW, AND
DECISION OF THE ADMINISTRATIVE LAW
JUDGE

John J. Mulrooney, II, Chief Administrative Law Judge. On February 2, 2012, the Administrator of the Drug Enforcement Administration (DEA or Government), issued an Order to Show Cause and Immediate Suspension of Registration (OSC/ISO) immediately suspending and proposing to revoke the DEA Certificate of Registration (COR), Number BC5289055, of Holiday C.V.S. L.L.C., d/b/a CVS/Pharmacy #00219 ("Respondent 219") pursuant to 21 U.S.C. 824(a), and to deny any pending applications for registration, renewal or modification pursuant to 21 U.S.C. 823(f) and 824(a). The same day, a similar OSC/ISO was issued against the DEA COR, Number BC6988298, of Holiday C.V.S. L.L.C., d/b/a CVS/Pharmacy #05195 ("Respondent 5195").

On March 2, 2012, the Respondents, through counsel, timely filed requests for hearing. On March 7, 2012, the two cases were consolidated. A consolidated hearing was held from April 25, 2012, through April 30, 2012, in Arlington, Virginia.

The issue ultimately to be adjudicated by the Administrator, with the assistance of this recommended decision, is whether the record as a whole establishes, by substantial evidence, that either (or both) of the Respondents' CORs should be revoked as inconsistent with the public interest, as that term is used in 21 U.S.C. 823(f) and 824(a).

After carefully considering the testimony elicited at the hearing, the admitted exhibits, the arguments of counsel, and the record as a whole, I have set forth my recommended findings of fact and conclusions of law below.

The Allegations

The OSC/ISOs issued by the Government against the Respondents contend that revocation of the Respondents' CORs is appropriate because "[s]ince at least 2010, [the Respondents] ha[ve] dispensed controlled substances to customers under circumstances indicating that the drugs are diverted from legitimate channels, misused or abused." ALJ Ex. 1, at 2; ALJ Ex. 2, at 2. The respective OSC/ISOs cite aggregate controlled substance purchase amounts and proffer that these numbers have been subject to increases, and allege that the Respondents "failed to exercise [their] corresponding responsibility regarding the proper prescribing and dispensing of controlled substances in violation of 21 C.F.R. § 1306.04(a) * * * failed to maintain effective controls against diversion of controlled substances in violation of 21 C.F.R. § 1301.76." ¹ ALJ Ex. 1, at 2; ALJ Ex. 2, at 2.

¹ On April 13, 2012, based on the factual proffers set forth in the respective prehearing statements, this tribunal issued an order ("Scope Order") which, *inter alia*, precluded the Government from introducing evidence of aggregate amounts of

The Stipulations of Fact

1) Respondents 219 and 5195, are retail pharmacies located in Sanford, Florida. Respondents 219 and 5195 are operated by CVS Pharmacy, Inc., ("CVS"), the division of CVS Caremark Corporation which operates the retail pharmacy business.

2) Respondent 219, is registered with DEA as a chain pharmacy in Schedules II–V under DEA registration number BC5289055 at 3798 Orlando Drive, Sanford, Florida 32773. Respondent 219's registration expires by its terms on December 31, 2013.

3) Respondent 5195, is registered with DEA as a chain pharmacy in Schedules II–V under DEA registration number BC6988298 at 4639 W 1st Street, Sanford, Florida 32771.

Respondent 5195's registration expires by its terms on December 31, 2013.

4) DEA served Administrative Inspection Warrants (AIWs) at Respondents 219 and 5195 on October 18, 2011.

5) An evaluation by DEA of aggregate controlled substance dispensing data from the Respondents' pharmacies resulted in DEA's decision to initiate the investigations that culminated in these proceedings. Tr. 130.

The Evidence

The Government's Evidence

The Government elicited factual testimony from six DEA Diversion Investigators (DI) and expert testimony from a retired professor from the College of Pharmacy at the University of Florida.

The Government's Fact Witnesses

DI Susan Langston, the Acting Diversion Program Manager for the Miami Field Division, testified that she has been a DI since 1996, and has held various supervisory positions prior to her current assignment as the Diversion Program Manager in Miami where she oversees the supervisors who manage six diversion investigator offices. Tr. 40–42.

Langston testified that "it's no secret that we have an incredible pill problem in the State of Florida. It's a national problem, but Florida is the epicenter." Tr. 43. According to DI Langston, the "pill problem is fueled by unscrupulous doctors and pill mill pain clinics * * * [that were] originally situated primarily in Broward County, and now [have] spread all over the state." Tr. 43. In Florida, "[t]he two most commonly abused drugs and the drugs that are a part of this pill

purchased controlled substances to establish that the Respondents continued registrations would be inconsistent with the public interest. ALJ Ex. 23. The Scope Order precluded the Government from introducing any evidence for a violation of 21 CFR § 1301.76 based on its failure to allege any factual basis in its OSC/ISO or initial or supplemental prehearing statements. *Id.*; ALJ Exs. 9, 16. The Scope Order also limited evidence the Respondents had noticed to meet the aggregate amount evidence and granted the Government's motion to limit expert testimony that related to the practice of medicine. ALJ Ex. 23.

mill problem * * * are oxycodone ² and alprazolam.³" Tr. 44.

Langston's testimony also included some background information related to recent changes in Florida law, and certain effects that those changes have had on the diversion enforcement landscape. In 2010, the State of Florida passed a law prohibiting doctors from dispensing Schedule II controlled substances from their offices to patients who paid with cash, check or credit card. Tr. 44–45. In July of 2011, the law was changed again to "virtually eliminate[] all dispensing of Schedule II and III controlled substances from doctors' offices." Tr. 45. DI Langston explained that in 2010, "98 of the top 100 doctors who dispensed oxycodone in the United States were in Florida [and that] there is more oxycodone that goes to the State of Florida than all of the other states combined." Tr. 45. DI Langston further testified that "as a result of the law change we've seen an incredible increase in the amount of pharmacies that are opening in the State of Florida and the amount of pharmacies that are now involved in the pill mill problem. All the [prescriptions for] drugs that the pill mill doctors write now in Florida have to be filled at a pharmacy." Tr. 46. This change is reflected in that fact that "[s]ome pharmacies that purchased hardly any oxycodone * * * now purchase three, four, five times the national average." Tr. 46.

In response to the increase in oxycodone sales, DIs in Florida have "visited hundreds of pharmacies over the past * * * two years [and have] talked to thousands of pharmacists." Tr. 47–47. The DEA has also sponsored a Pharmacy Awareness Conference in West Palm Beach, Florida. Tr. 47. Langston explained that, when interacting with pharmacists, DEA representatives go over the rules and regulations that pharmacies must follow * * *. We talk about what we're seeing in Florida * * * We talk about trends. We talk about what we're seeing doctors doing, what we're seeing happening at the patient level.⁴ We talk about the red flags of diversion, types of things to look out for whenever they're filling prescriptions.

Tr. 47–48. As an example of a red flag of diversion which would have been discussed during these DEA outreach programs, DI Langston identified "a lot of prescriptions coming in for oxycodone, 30 milligrams (mg), oxycodone, 15 [mg]; Xanax ⁵ [alprazolam] two [mg]." Tr. 48.

As a part of its outreach activities, the DEA, at the request of CVS counsel John

² "A medicinal substance used as a narcotic and analgesic." 4–O Attorneys' Dictionary of Medicine O–85581. Oxycodone is a Schedule II controlled substance. 21 CFR § 1308.12(b)(1).

³ "A drug used in the treatment of anxiety and panic disorders usually associated with depression." 1–A Attorneys' Dictionary of Medicine A–5091. Alprazolam is a Schedule IV controlled substance. 21 CFR § 1308.14(c).

⁴ When conducting these outreach activities, Ms. Langston has observed that "virtually every pharmacist" knows about the pill mill problem. Tr. 47.

⁵ Xanax is "[t]he brand name of a preparation containing alprazolam, used in the treatment of anxiety." 6–X Attorneys' Dictionary of Medicine X–125138.

Gilbert, Esq.,⁶ conducted a meeting with CVS representatives on December 8, 2010 ("December 2010 CVS Meeting"). Tr. 48–49. DI Langston explained that prior to the meeting Mr. Gilbert contacted her by telephone "and said that CVS was aware of the pill mill problem in South Florida, and he would like to meet with us and bring a couple of the supervisors along that worked for local CVS stores and talk about the pill mill problem, oxycodone diversion problem, and what types of things we're seeing." Tr. 49. In preparation for the meeting, DI Langston ran an ARCOS⁷ report for the oxycodone purchases of Respondent 219 from 2006 through 2010. Tr. 58.

The December 2010 meeting was attended by: Mr. Gilbert; Jennifer Lalani, a supervisor for CVS stores 219 and 5195; Ms. Tankut, an official from CVS's corporate headquarters in Rhode Island; DI Langston; DEA Diversion Group Supervisor (GS) Gayle Lane; DI Phyllis Garret; Robert Difiore, a pharmacist from the Florida Department of Health; and Michele Miller, a supervisor from the West Palm Beach Department of Health. Tr. 49–51, 69.

At the meeting, the parties discussed a pharmacist's corresponding responsibility "at length." Tr. 54. The discussion topics included the pill mill problem in Florida; some recent arrests and other DEA enforcement activity; increased publicity; the oxycodone crisis; and the combination of prescriptions for oxycodone 30 mg, oxycodone 15 mg, Alprazolam 2 mg, and a fourth "filler"⁸ drug, which DEA identified as an indicator of diversion.⁹ Tr. 51–52.

The DEA representatives identified some indicators of possible diversion to be aware of, such as "patients driving distances to see their doctors, patients driving distances to go to particular pharmacies, some people going from out of state * * *," and monitoring for "suspicious behavior." Tr. 52. "Suspicious behavior" was defined as "[p]eople coming and appearing like they may not need the medication, appearing like they may be high, things like that." Tr. 53. Other red flags discussed were: (1) large quantities of people paying cash; (2) large quantities of people traveling distances to see the prescribing physician; (3) people coming in with the same prescriptions and same diagnoses (particularly lower lumbar pain); and (4) an "influx" of prescriptions from board certified pediatricians or gynecologists.¹⁰ Tr. 54–57.¹¹

⁶ An attorney of record for the Respondents in this matter.

⁷ The Automation of Reports and Consolidated Orders System (ARCOS) is a DEA database which monitors the flow of controlled substances.

⁸ Soma, ibuprofen, Flexeril and blood pressure medication were identified by DI Langston as possible "filler" drugs. Tr. 51–52. Langston explained that "filler drugs [are] medication[s] that doctors will prescribe so it won't look like they're prescribing too many controlled substances." Tr. 51–52.

⁹ Also during the meeting, Ms. Lalani stated that CVS "had seen an increase in the numbers of prescriptions for oxycodone * * * and that's why they wanted the meeting." Tr. 52.

¹⁰ Ms. Langston estimated that "90 percent of the pill mill doctors use lower lumbar pain" as a diagnosis code. Tr. 56.

¹¹ On cross-examination Ms. Langston agreed that, standing alone, none of the red flags she listed

In addition to red flags, the meeting participants discussed methods to verify a prescription. Tr. 57. Specifically, the DEA representatives stated that "[s]imply calling a doctor's office to verify that he or she wrote a prescription does not meet the requirement [of verification]." Tr. 57. The representatives for CVS agreed with this assessment. Tr. 57. After the CVS representatives were shown the oxycodone ordering of Respondent 219, they appeared "a little bit surprised at quite how high it was, and they said they didn't know why it was so high." Tr. 59. Ms. Lalani speculated that the high numbers could have been caused by the fact that Respondent 219 was a 24-hour store and assured those present that she would look into Respondent 219 to ensure that everything was being done legitimately.¹² Tr. 59.

DI Langston testified that over the past year, "at least" thirty doctors and three pharmacists had been arrested "for their part in oxycodone diversion." Tr. 59–60. Simultaneously, "[t]he State of Florida * * * picked up their efforts [by] issu[ing] emergency suspensions on several doctors' medical licenses over the past year." Tr. 60. When a Florida State license is subject to an immediate suspension order, a notification of the suspension is placed on the Florida Department of Health's Web site "within ten minutes." Tr. 61. Similarly, the DEA Web site for DEA registrants updates a registrant's profile the same day a DEA immediate suspension order is served on the effected registrant.¹³ Tr. 62.

The Government elicited information from DI Langston about the prescription privileges of a physician named Dr. Ronald Lynch. Tr. 66. Langston testified that Dr. Lynch's DEA COR was revoked, effective January 18, 2011, and that as of the effective date of that revocation order, he no longer enjoyed the authority to prescribe, administer or dispense any controlled substances. Tr. 66; *see also*, Gov't Ex. 32 at 3–12. Although Dr. Lynch's COR was revoked, DI Langston explained that the DEA Web site would reflect that his registration was "expired." Tr. 74–75.

On cross-examination DI Langston testified that, unlike the case of a revocation, in situations where a COR expires by its own terms, there is a thirty-day window between the expiration date and the date the number associated with the COR is retired. Tr. 78–79. This grace period is designed to address inadvertent lapses or other unintentional delays. If a registrant submits an application for renewal after the expiration date, but during the grace period, then the registrant will maintain his or her dispensing

were dispositive on the issue of the legitimacy of a prescription. Tr. 90–94.

¹² On cross-examination Ms. Langston testified that she addressed the oxycodone ordering at Respondent 5195 at the December 2010 CVS Meeting, but did not provide the underlying data. Tr. 81–82. However, in a January 25, 2012, summary of the December 2010 CVS Meeting sent to DEA's Chief Counsel Office, Ms. Langston did not state that she addressed Respondent 5195's oxycodone ordering. Tr. 82.

¹³ The DEA registrant Web site referenced by Ms. Langston is a system which a DEA registrant can log in to verify that another registrant has a valid DEA registration. Tr. 63–64.

privileges. Tr. 78–79. A pharmacist who encounters an "expired" signal may resolve the red flag by calling the DEA and inquiring about the status of the application or registration. Tr. 102–03.

The testimony presented by DI Langston was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also presented the testimony of DI Stephanie Orr. DI Orr testified that she has been employed by the DEA since July of 2009, and that she currently is stationed in the DEA's Boston Office. Tr. 335–36.

DI Orr testified that she participated in the execution of an administrative inspection warrant on Respondent 219 on October 18, 2011, and that her role in that evolution was "to gather the records of inventories and prescription records and dispensing records." Tr. 337–38. Upon entering the store, DI Orr enlisted the assistance of CVS lead technician Keyla Perry in gathering records at the pharmacy Tr. 337–40. Through Ms. Perry, DI Orr collected an inventory taken in September of 2011, and another taken in October of 2010.¹⁴ Tr. 339. Orr also requested and received hard copy "prescriptions for the controlled substances for Schedule 2s * * * for that time period." Tr. 339–40. The prescription records, which were produced in small boxes, were photocopied by the DEA, and then returned Respondent 219. Tr. 340–41. DI Orr also obtained the dispensing binders¹⁵ for oxycodone 30 mg for the relevant time period. Tr. 341–42. As with the hard copies of the prescriptions, the dispensing labels were taken into DEA evidence, scanned, and returned. Tr. 342.

While Ms. Perry assisted with the collection of records, she and DI Orr discussed Perry's employment at CVS. Tr. 343. Orr described Perry's demeanor during this conversation as "normal" and "relaxed." Tr. 343. Ms. Perry stated that she had worked for CVS for seven years, and Respondent 219 for the past three years. Tr. 343. Ms. Perry also told DI Orr that Respondent 219 filled approximately a thousand prescriptions per day, the majority of which were for controlled substances. Tr. 344.

As to the filling of oxycodone 30 mg prescriptions, Ms. Perry indicated that Drs. Pyko, Namone, Moyer, Pizza, Scolaro, Namone, Moyer and Zerkowitz "were some of the top prescribing doctors" for oxycodone 30 mg at Respondent 219. Tr. 344. Ms. Perry also set forth Respondent 219's procedure for verifying Schedule II controlled substances presented to the pharmacy. Tr. 345. Specifically, Ms. Perry "stated that when a prescription was presented she'll get an ID from the patient, write down their driver's license number on the prescription, and then call the doctor to verify and write down who they spoke to, the date, along with * * * the diagnosis code." Tr. 345.

¹⁴ DI Orr explained that she "gathered two sets of inventories because [she] wanted to make sure that it went over at least a year." Tr. 339.

¹⁵ DI Orr explained that "when a prescription is printed out [Respondent 219] put a sticker on the back of the prescription and then that [sticker] has like a label and they put that in a binder." Tr. 341.

After the AIW inspection, DI Orr received a CD that contained a Microsoft Excel spreadsheet (CVS Dispensing Data)¹⁶ that was provided by CVS and contained the dispensing records for the Respondent pharmacies from January 1, 2010, up until October 16, 2010.¹⁷ Tr. 347. DI Orr also received “one scrip that was labeled 10/17/11.” Tr. 348. Orr narrated her understanding of the information provided in the spreadsheet provided by CVS. In addition to the drug type and strength, the CVS Dispensing Data set forth culled information regarding individual controlled substance dispensing events. The document included the method of payment (listed under “agency type”), the National Drug Code and schedule classification for each drug, the pharmacy number (219 or 5195), the prescription number assigned by the Respondents to specific dispensings, the dispensing date and quantity, as well as the name and address of each patient and prescriber. Tr. 353–56; Gov’t Ex. 30. DI Orr invested considerable testimony into detailed explanations of her efforts to process the data provided by CVS into multiple spreadsheets to facilitate an analysis of the Respondents’ dispensing.

Sometime after receiving the CVS Dispensing Data, DI Orr “was sent an email from [Group Supervisor] Carter [containing] about 22 different spreadsheets for different doctors that [were] provided to her from CVS.” Tr. 365. These individual spreadsheets showed the controlled substances dispensed pursuant to prescriptions of certain practitioners. *Id.* DI Orr was asked “to analyze [all the spreadsheets], look through [them], and create several spreadsheets for different physicians and addresses, and then sort it by drugs.” Tr. 350. In this regard, Orr explained that she utilized specialized training she had received at DEA regarding the handling and preparing of spreadsheets. Tr. 535.

Though the spreadsheets purport to reflect the dispensing records of the Respondents, DI Orr conceded that the “actual”¹⁸ dispensing records are the hard copies of the prescriptions, and that the overall reliability of the spreadsheets provided was dependent on the reliability of the pharmacy technicians entering the dispensing data. Tr. 542–43. To ensure the accuracy of the data provided, DI Orr compared the hard copies of “more than one-hundred” prescriptions to the corresponding data reflected in the CVS Dispensing Data. Tr. 537–38. Of the hard

copy prescriptions she checked against the CVS Dispensing Data, DI Orr identified “several” errors. Tr. 544. When queried why she would check only one-hundred prescriptions in a document with approximately 25,000 records of dispensing, DI Orr testified that she did not have time to perform a more thorough analysis. Tr. 555.

A spreadsheet of common addresses (Common Address Spreadsheet) was created by DI Orr by culling address information from the CVS Dispensing Data Tr. 358–60; Gov’t Ex. 22. Orr explained that the filtering process utilized to create the Common Address Spreadsheet involved a manual survey of only approximately one-fourth of the CVS Dispensing Data. Tr. 360–61. From this manual view, DI Orr identified dispensing events for “multiple people living at the [same] address, the same household * * *.” Tr. 362. The dispensing events for common addresses were then populated into the Common Address Spreadsheet, which was received into evidence. Gov’t Ex. 22.

DI Orr also created a spreadsheet from the CVS Dispensing Data wherein she culled out oxycodone 30 mg dispensing events grouped by thirteen individual Florida prescribers. Tr. 367–68. From the prescriber-culled data, DI Orr created “pivot tables”¹⁹ for each practitioner, showing the sum of oxycodone 30 mg prescribing, and in some cases the sum of Roxycodone 30 mg prescribing. *See* Tr. 368. The combined by-prescriber data and pivot tables (By-Prescriber Chart A) were received into evidence. Gov’t Ex. 57.

The By-Prescriber Spreadsheet was, in turn, used by DI Orr to create a pivot table setting forth the total oxycodone 30 mg dispensed by the Respondent pharmacies pursuant to prescriptions written by the thirteen South Florida doctors organized by patients residing in specific cities and states (Prescriber & Patient Address Chart). Tr. 381; Gov’t Ex. 58. When creating the categories for the locations, DI Orr aggregated addresses she believed to be the same, explaining that “[a]n example might be Altamonte Springs and they might put ALT Springs but you know it was Altamonte Springs.” Tr. 383. As with the By-Prescriber Spreadsheet,²⁰ the source of the data used in Prescriber & Patient Address Chart was the individual prescriber spreadsheets provided to the DEA by CVS. Tr. 384.

Orr also created a document which combined spreadsheets and pivot tables to demonstrate the dispensing of oxycodone 30 mgs by Respondent pharmacies pursuant to prescriptions written by four specific South Florida practitioners (By-Prescriber Chart B). Tr. 439–40; Gov’t Ex. 59. To create By-Prescriber Chart B, DI Orr extracted from the CVS Dispensing Data, dispensing events for oxycodone 30 mg, Roxycodone 30 mg, and Oxycontin 30 dispensed pursuant to prescriptions written by the four South Florida doctors. Tr. 440, 445. The extracted data was then separated into four spreadsheets, with each spreadsheet representing the oxycodone 30 mg, Roxycodone 30 mg, and Oxycontin 30 mg

dispensing for a particular doctor. Tr. 440–41. DI Orr then created pivot tables for each spreadsheet representing the total amount of oxycodone 30 mg dispensed, and the total amount of oxycodone 30 mg dispensed to specific United States cities. Tr. 439–444.

In response to a request from DEA, CVS generated and provided to the DEA a spreadsheet that culled out controlled substance dispensing events by the Respondent pharmacies pursuant to prescriptions written by Dr. Ronald Lynch.²¹ Gov’t Ex. 32. Orr removed the header from the CVS spreadsheet, but otherwise did nothing to change the document, which was received into evidence (Lynch Dispensing Chart). Tr. 454; Gov’t Ex. 32.

Orr generated two pivot tables from the Lynch Dispensing Chart: one table showing the total amount of specific controlled substances dispensed by the Respondent pharmacies pursuant to prescriptions written by Dr. Lynch (Lynch By-Medication Table) and the other table showing the total amount of controlled substances prescribed by Dr. Lynch and dispensed by Respondent pharmacies to patients, organized by the address cities of the patients (Lynch By-Patient City Table). Tr. 457–58; Gov’t Ex. 33 at 1–3.

DI Orr explained that she was aware that Dr. Lynch’s DEA registration was revoked on January 18, 2011,²² and that she searched the Lynch Dispensing Chart²³ for controlled substance dispensing events occurring after the January 18, 2011, revocation date. Tr. 460–61. DI Orr found three instances where Schedule II controlled substances were dispensed for a patient named T.N. after January 18, 2011, and obtained the corresponding hard copies and dispensing labels. Tr. 461–62; Gov’t Ex. 33 at 4–9; Gov’t Ex. 32 at 9. The three prescriptions were written for T.N. for sixty tablets of 10/650 mg Percocet. For all three prescriptions, the prescribing physician is listed as Ronald Lynch, M.D., of Lake Mary, Florida. Gov’t Ex. 33, at 4, 6, 8. The earliest of these bares the issuance date of February 2, 2011. Gov’t Ex. 33, at 4. The corresponding dispensing label for that prescription reflects that on February 2, 2011, at 7:04 p.m., sixty tablets of 10–650 mg Endocet were dispensed for patient T.N. *Id.* at 5. Another prescription written by Dr. Lynch for T.N. is dated February 25, 2011. Gov’t Ex. 33, at 6. The corresponding dispensing label indicates that on February 25, 2011, at 2:02 p.m., sixty tablets of oxycodone-Acetaminophen 10–650 were dispensed. *Id.* at 7. A third prescription is dated March 24, 2011. *Id.* at 8. The

¹⁶ The spreadsheet from CVS was admitted into evidence as Government Exhibit 30.

¹⁷ Though the data on the spreadsheet came from CVS, DI Orr testified that it was her understanding that the data was sent via email to another DI who burned the data onto a CD. Tr. 348. Although the DEA had only requested the dispensing records for only oxycodone 30 mg, the spreadsheet provided by CVS also contained other controlled substances, such as Oxycontin 80 mg and Oxycontin 20 mg. Tr. 350.

¹⁸ DI Orr explained that “they typically have three kind[s] of dispensing records], the hard copies, the electronic copy, and then also the binder that has the other stickers.” Tr. 544. DI Orr “found missing prescriptions,” where a copy or record would not have a corresponding entry in another location. Tr. 544.

¹⁹ A pivot table is “a tool through Excel that “breaks * * * up [data] more specifically.” Tr. 368.

²⁰ Gov’t Ex. 57.

²¹ The information was provided to another DI and forwarded to Orr. Tr. 453.

²² As set forth above, the record evidence establishes that on December 3, 2010, DEA issued a revocation order, effective January 18, 2011. Gov’t Ex. 31 at 3–12; *Ronald Lynch M.D.*, 75 FR 78745 (2010). In the order revoking the COR, the Agency found that Dr. Lynch had engaged in the unauthorized practice of medicine and had issued prescriptions which “lacked a legitimate medical purpose.” *Lynch*, 75 FR at 78753.

²³ DI Orr limited her search to Schedule II controlled substances because she “had only requested Schedule II hard copy prescriptions * * * so anything else I wasn’t able to verify hard copies.” Tr. 462.

corresponding dispensing label for this prescription reflects that on March 24, 2011, at 12:42 p.m., sixty tablets of oxycodone-Acetaminophen 10–650 were dispensed. *Id.* at 9. All three controlled substance dispensing events occurred after Dr. Lynch's January 18, 2011, revocation date, when Lynch had no authority to prescribe controlled substances. All three dispensing events occurred at Respondent 219. Gov't Ex. 32 at 9. Further, the Lynch Dispensing Chart reflects that Respondent 219 dispensed controlled substances pursuant to prescriptions written by Dr. Lynch no fewer than twenty-seven (27) times after Dr. Lynch's COR was revoked. Gov't Ex. 32. Of these twenty-seven prescriptions, seven were dispensed later than June of 2011. Gov't Ex. 32, at 5, 7. Similarly, Respondent 5195 filled four prescriptions after the January 18, 2011, revocation, one of which fell in June. Gov't Ex. 32, at 12. Thus, the Respondent pharmacies were dispensing controlled substances on Dr. Lynch's prescriptions approximately six months after he had lost his authority to prescribe them.

DI Orr also queried the CVS Dispensing Data for prescriptions for controlled substances dispensed pursuant to prescriptions written by Dr. Anthony Wicks, a physician with offices located in Winter Springs, Florida. These prescriptions were targeted because Orr was aware that Dr. Wicks' DEA COR expired on May 11, 2011. Tr. 468. DI Orr created a chart setting forth oxycodone 30 mg dispensing events from Respondent 219 (Wicks 219 Dispensing Chart) and Respondent 5195 (Wicks 5195 Dispensing Chart), as well as a chart reflecting combined dispensing events from both pharmacies regarding those prescriptions from Dr. Wicks. (Wicks Combined Dispensing Chart). Tr. 464–70; Gov't Exs. 10, 27 at 1–8, 28 at 1–7. DI Orr also compared the Wicks dispensing events reflected in the two charts with hard-copy prescription scrips of the medications dispensed at those pharmacies. Gov't Exs. 27 at 9–58, 28 at 8–37. An analysis of the data revealed thirty-eight (38) dispensing events where Respondent 219 dispensed controlled substances for Wicks prescriptions after his DEA COR expired on May 31, 2011. Tr. 468. Respondent 5195 dispensed controlled substances seventeen (17) times pursuant to Wicks' prescriptions after Wicks' COR expired. Tr. 469. Thus, the two Respondent pharmacies filled a total of fifty-five (55) oxycodone prescriptions written by Dr. Wicks after his COR was expired and he was without authority to write controlled substance prescriptions. Respondent 5195 filled Dr. Wicks' oxycodone prescriptions as late as July 14, 2011, and Respondent 219 dispensed Wicks' oxycodone prescriptions as late as July 15, 2011. Gov't Ex. 10 at 6.

The record also establishes that even prior to the expiration of his COR, Dr. Wicks had a COR-registered address, not in Florida, but in California. Gov't Ex. 26; Tr. 580. Notwithstanding that reality, and the legal requirement to have a COR-registered address in the state where a prescriber is prescribing,²⁴ from December 17, 2010,

through May 31, 2011, Respondent 219 dispensed 117 controlled substance prescriptions on prescriptions issued by Wicks. Gov't Ex. 27. Respondent 5195 dispensed 125 controlled substance prescriptions on Wicks' California-address COR during the same period. Gov't Ex. 28.

At DEA's request, CVS supplied dispensing data on an Orlando, Florida prescribing physician, named Dr. Riyaz Jummani (Jummani Dispensing Chart).²⁵ Gov't Ex. 35; Tr. 472–74. Using the data in the Jummani Dispensing Chart, DI Orr created two pivot tables: a table showing the total amount of specific types of drugs dispensed by the Respondent Pharmacies pursuant to prescriptions written by Dr. Jummani (Jummani By-Medication Table);²⁶ and a table organizing Dr. Jummani dispensing events at the Respondent pharmacies by patient address city/state (Jummani By-Patient Location Table). Gov't Ex. 36 at 2–4.²⁷

At DEA's request, CVS supplied dispensing data from the Respondent pharmacies on a Palm Coast, Florida, prescriber named Dr. Ralph Chambers (Chambers Dispensing Chart).²⁸ Gov't Ex. 44; Tr. 478–79. Using the data from the Chambers Dispensing Chart, DI Orr created two pivot tables. The first table shows "the [types of] drugs that [Dr. Chambers] prescribed that were dispensed at CVS 5195 and 219" (Chambers By-Medication Table). Gov't Ex. 45 at 1. The second table shows "Dr. Chambers' dispensing records per city and state and quantity" (Chambers By-Patient Location Table). Gov't Ex. 45 at 2–3; Tr. 481.

At DEA's request, CVS supplied dispensing data from the Respondent pharmacies on a Winter Park, Florida, prescriber named Dr. Michael Moyer (Moyer Dispensing Chart). Gov't Ex. 48. The spreadsheet was sent by CVS to Investigator Carter, who then forwarded it to DI Orr. Tr. 482–84. Using data from the Moyer Dispensing Chart, DI Orr created a pivot table showing total amount of specific types of drugs dispensed by the Respondent pharmacies pursuant to prescriptions written by Dr. Moyer (Moyer By-Medication Table).²⁹ Gov't Ex. 49; Tr. 482.

At DEA's request, CVS supplied dispensing data from the Respondent pharmacies on a Longwood, Florida, prescriber named Dr. James Pizza (Pizza Dispensing Chart).³⁰ Gov't Ex. 55; Tr. 485–88. From the Pizza

Dispensing Chart, DI Orr generated a pivot table and pie chart setting forth aggregate numbers of three oxycodone medications (oxycodone HCL 15 MG, oxycodone HCL 40 mg, Roxicodone 15 mg or Roxicodone 30 mg) reflected in dispensing events from the Respondent pharmacies from July 19, 2010, through October 17, 2011 (Pizza Pie Chart and Table). Gov't Ex. 56 at 1. Orr also used the Pizza Dispensing Chart to generate a table organizing Dr. Pizza dispensing events at the Respondent pharmacies by patient address city/state (Pizza By-Patient Location Table). Gov't Ex. 56 at 2–4; Tr. 487–89.³¹

The testimony presented by DI Orr was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also presented the testimony of GS Kyle Wright. Tr. 309. GS Wright testified that he began his employment with the DEA in 1995, and served as a DI, and held various supervisory positions in the agency prior to his current assignment as the Unit Chief of DEA's Targeting and Analysis section, also known as ARCOS. Tr. 309–11.

GS Wright explained that distributors and manufacturers of Schedule I through III controlled substances are required by law to report "[a]ny transaction involving those controlled substances." Tr. 311. The ARCOS section compiles the reports of the distributors and manufacturers and uses this data to fulfill internal requests from the DEA and internal requests from organizations like the United Nations, newspapers, and State attorney general offices. Tr. 312.

In his capacity as Unit Chief of ARCOS, Mr. Wright was asked to provide an overhead map of the Respondents' pharmacy locations and "other pharmacies within the immediate area." Tr. 313. Mr. Wright testified that Government Exhibit 19, which shows the location of the Respondent Pharmacies, as well as other pharmacies in the area, was created using Google Maps. Tr. 313. Also using Google maps, Mr. Wright's unit produced a "clean" map of Central Florida. Tr. 316–17. The clean map was admitted as Government Exhibit 63.

Mr. Wright testified to the creation of Government Exhibit 62. Tr. 317–18. Government Exhibit 62 is a map which marks the city of Sanford, and "the other townships or cities located in southern Florida, in which prescribing doctors resided or operated their offices at,"³² but whose prescriptions were being filled in Sanford." Tr. 318. The map shows the "relative distance" between the cities of the prescribing physicians and the city of Sanford, where the Respondent pharmacies are located. Tr. 317–18. Government Exhibit 62 does not differentiate between the number of prescriptions filled, the dates prescriptions were filled, or whether the prescriptions

²⁵ This data was provided to another DI and forwarded to Orr. Tr. 473.

²⁶ Gov't Ex. 36 at 1.

²⁷ On cross-examination DI Orr admitted that two pages that the Government had initially included as part of Government Exhibit 36 actually depicted prescription scrips from a different prescriber which were not problematic. Tr. 476. The Government withdrew these two pages and the Respondents offered it to show a lack of Government infallibility, and handwritten markings on the scrip to establish that their pharmacists were conducting some measure of due diligence in an effort to resolve potential red flags. Tr. 549; Resp't Ex. 94.

²⁸ This data was provided to another DI and forwarded to Orr. Tr. 478–79.

²⁹ This data was provided to another DI and forwarded to Orr. Tr. 482–83.

³⁰ This data was provided to another DI and forwarded to Orr. Tr. 485.

³¹ The dispensing records contained in the CVS Dispensing Data only went through October 16, 2011. Tr. 502. At some point after the October 18, 2011, AIW, CVS provided the dispensing data for October 17, 2011, to a DI who forwarded the data to DI Orr. Tr. 502–03.

³² The locations of the prescribing physicians were provided to Mr. Wright by another component of DEA. Tr. 319.

²⁴ 21 CFR 1301.12.

were filled at Respondent 219 or Respondent 5195. Tr. 329.

ARCOS personnel also used Google Maps to create a map of central Florida, showing the CVS pharmacies located “within the Orlando and Daytona Beach, Florida area.” Tr. 321. The map of the other CVS pharmacies, which was admitted as Government Exhibit 17, contains a key which matches the marks on the map to specific CVS pharmacies. Tr. 321. ARCOS personnel obtained the locations of the CVS pharmacies marked in Government Exhibit 17 from the DEA’s CSA database, which is a database of information provided to the DEA by DEA registrants. Tr. 322. Specifically, ARCOS personnel queried the CSA database for all pharmacies in Florida, and then selected pharmacies named “CVS” with specific zip codes. Tr. 322–24. The key associated with Government Exhibit 17 was downloaded directly from the CSA database. Tr. 324.

Government Exhibit 64 was created by the ARCOS section to show the locations of the Respondent Pharmacies “relative” to the locations of other CVS pharmacies and to the “practitioners * * * identified as having prescriptions filled at one of [the Respondent] pharmacies.” Tr. 325–26. Put differently, Government Exhibit 64 shows three classes of information: (1) the location of the Respondent Pharmacies (marked in green); (2) the location of other CVS pharmacies in the Sanford area (marked in blue); and (3) the location of practitioners whose prescriptions were filled at the Respondent Pharmacies (marked in red). *Id.* As with Government Exhibit 17, the locations of the CVS pharmacies were taken from the CSA database. Tr. 327. The locations of the prescribing practitioners were provided by DEA’s Chief Counsel’s Office. Tr. 327. As with Government Exhibit 62, Government Exhibit 64 does not differentiate between the number of prescriptions filled, the dates prescriptions were filled, or whether the prescriptions were filled at Respondent 219 or Respondent 5195. Tr. 329–30.

The testimony presented by GS Wright was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also presented the testimony of Heather Wehrle, a DI with the Nashville District Office. Tr. 163. DI Wehrle has been employed by the DEA for over eight years, and has attended various in-house DEA training evolutions. Tr. 164–65.

DI Wehrle was a part of the group that served the AIW on Respondent 5195 on October 18, 2011. Tr. 165–66. According to Wehrle, she arrived at Respondent 5195 in support of the AIW at approximately 10:30 a.m., and two hours thereafter, conducted an interview with Marcus Badley, a pharmacy technician who was on duty. Tr. 166–68. At some point during the interview, Badley walked “in the direction of the drive-through window” and retrieved a 3½ by 5 inch handwritten piece of paper. Tr. 174–75. The paper had the words “do not fill” written across the top, and the names of four doctors written (in different handwriting) below.³³

³³ DI Wehrle wrote the names of the doctors on the “do not fill” list down in her notes; but she did not take the list itself. Tr. 196–97.

Tr. 174–75. The four names listed on the document were: (1) Dr. Pizza; (2) Dr. Moyer; (3) Dr. Mammone; and (4) Dr. Jummani. Tr. 174. Mr. Badley stated that the names on the list were doctors that the pharmacy “look[ed] out for that have been in trouble.” Tr. 204. DI Wehrle did not learn when the list was created. Tr. 198. Also during the interview Mr. Badley stated that Respondent 5195 only would fill prescriptions in the “Central Florida area.” Tr. 175.

DI Wehrle also interviewed five or six customers present at the store at the time of the AIW. Tr. 176. Two of the customers had prescriptions written by Dr. Pizza. Tr. 177–78. One customer had dilated pupils and difficulty concentrating. Tr. 177–78. However, there is no evidence that any of the customers DI Wehrle interviewed had prescriptions filled at Respondent 5195 that day. Tr. 178.

Ten days after the AIW inspection, on October 28, 2011, DI Wehrle interviewed a Respondent 5195 pharmacist named Mark Mascitelli. Tr. 178–80. The interview was conducted at the DEA Office in Orlando, and was attended by DEA GS Ruth Carter, and CVS attorneys John Gilbert, Esq. and Meredith Young, Esq. Tr. 178–79. Pharmacist Mascitelli stated that he had been employed by CVS since August of 2009, and that he had been employed as a full time employee at Respondent 5195 since May of 2010. Tr. 180.

Pharmacist Mascitelli told DI Wehrle that, although the pharmacy opens at 8:00 a.m., customers “start showing up early.” Tr. 180–81. He also told the DEA investigators that “he could fill oxycodone prescriptions all day long if he had the manpower and the inventory.” Tr. 181. However, Mascitelli stated that “whoever opens in the morning * * * has to set limits on how many oxycodone prescriptions are filled for the day due to inventory. Tr. 182. Pharmacist Mascitelli said that Respondent 5195 would not fill prescriptions for Dr. Pizza, Dr. Mammone, Dr. Chambers or Dr. Scolero because of actions taken against the doctors’ licenses. Tr. 183. DI Wehrle did not inquire what steps were taken when a prescription from one of these doctors was presented; or when Mascitelli developed his concerns about the physicians. Tr. 199.

Mr. Mascitelli explained that approximately two weeks prior to the serving of the AIW, CVS supervisor Jennifer Lalani told him and Jessica Merrill—the Pharmacist in Charge (“PIC”) at Respondent 5195—that they “were to identify more filters³⁴ to put in place for oxycodone prescriptions.” Tr. 185. In response to this directive, Pharmacist Mascitelli and PIC Merrill, “decided [to] no longer accept new customers of oxycodone prescriptions * * * that they needed to look for signs of abuse or impairment [and that they needed to do more verifications on the customers.” Tr. 186. The pharmacy also decided to limit filling prescriptions for only those patients within the Deland to Orlando, Florida, area. Tr. 201.

That same day, DI Wehrle conducted an interview with Marie Morrell, the lead

pharmacy technician at Respondent 5195. Tr. 186–87. Like the interview with Pharmacist Mascitelli, GS Carter, and CVS attorneys John Gilbert Esq. and Meredith Young, Esq. were also present during the discussion. Tr. 187. Ms. Morrell testified it was part of her responsibility to receive prescription scrips from Respondent 5195’s pharmacy customers. Tr. 187. All Schedule II controlled substance scrips would be taken directly to the pharmacist. Tr. 187–88. If the pharmacist determined that the medication would be dispensed, “then the customer [was] told * * * that it would be five to six hours before their prescription [was] filled.”³⁵ Tr. 188. Based “on inventory and man hours” limits would be placed on the number of oxycodone prescriptions which could be filled for one day.” Tr. 188–89. The limit would be satisfied “on a first-come, first-served basis.” Tr. 189. According to Morrell, the limit was sometimes reached between 10:00 a.m. and noon; but the limit could be reached as early as 8:30 a.m. (i.e., 30 minutes after the pharmacy opens). Tr. 189. In addition to the foregoing duties, Ms. Morrell also engaged in “customer verifications.” Tr. 187–88. In this regard, Morrell related that: “she normally * * * w[ould] call the doctor’s office [and] verify[] the diagnosis code if there is one on the prescription. If there is not one, she w[ould] get one from the doctor and put it on there. If the customer has seen multiple doctors, she may call [the] other doctors’ offices * * * She w[ould] also establish from the doctor how long that person has been a patient of the doctor’s.” Tr. 188. As to the behavior of the customers, Morrell told Wehrle that she looked “for any signs of rude behavior, rude language, inconsistencies in stories [and] hat and sunglasses.” Tr. 190.

On November 3, 2011, DI Wehrle interviewed a CVS pharmacist named Randy Dwight. Tr. 190. Mr. Dwight told DI Wehrle that he was a “floater pharmacist” for CVS and that he covered twenty stores in two districts. Tr. 191. He worked at Respondent 5195 once, and worked at Respondent 219 “every other weekend.” Tr. 191–92. Mr. Dwight explained that these two pharmacies did not fill controlled substances on nights or weekends “because they cannot contact the doctor’s office.” Tr. 191–92.

The testimony presented by DI Wehrle was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also presented the testimony of GS Ruth Carter. Tr. 213–14. GS Carter, a 23-year veteran of DEA, currently serves as the Group Supervisor for DEA’s Seattle Field Division. Tr. 214.

Carter testified that she became involved with the investigation into the Respondent Pharmacies in October of 2011, when she was assigned as the case agent in a case involving Cardinal Health, a distributor of controlled substances to CVS. Tr. 216. In connection with the Cardinal Health investigation, GS Carter reviewed the

³⁴ DI Wehrle testified that she understood “filters” to mean procedures “[t]o catch bad stuff, bad things going through the pharmacy.” Tr. 186.

³⁵ If the prescription was for a Schedule III through Schedule V drug, then Ms. Morrell would prepare the bottles and labels for the prescription to be filled. Tr. 187–88.

controlled substance ordering data for CVS stores supplied by Cardinal. Tr. 217. Carter testified that, while reviewing the data, she became “very concern[ed]” about the quantity of oxycodone ordered by the Respondent Pharmacies. Tr. 217. It was based on Carter’s discomfiture that DEA prepared administrative inspection warrants for the Respondent Pharmacies. Tr. 217. The AIWs were executed at both Respondent pharmacies on October 18, 2011, and GS Carter participated on scene at Respondent 5195. Tr. 218.

During the execution of the AIW at Respondent 5195, GS Carter interviewed employees and examined records. Tr. 218. GS Carter testified that she arrived at Respondent 5195 sometime between 10:00 a.m. and 10:30 a.m. Tr. 219. Upon arriving at Respondent 5195, a special agent presented the AIW to PIC Jessica Merrill. Tr. 219. While the AIW was presented to PIC Merrill, GS Carter observed two individuals sitting in the waiting area next to the pharmacy counter. Tr. 219. One of the individuals volunteered that he had driven “far” to get his prescription for oxycodone filled, but that he had been told by pharmacy technician Arlene Piccerilli that the store was out of stock. Tr. 220–21.

GS Carter then interviewed Ms. Piccerilli, who said that she had been employed at Respondent 5195 for approximately thirty months. Tr. 222. She also admitted that the pharmacy was not out of oxycodone. Tr. 224–25. When GS Carter inquired why Ms. Piccerilli had just told a customer that the store was out of oxycodone,³⁶ Piccerilli replied that “the pharmacist on duty sets a limit of how many oxycodone prescriptions can be filled each day.” Tr. 223. On October 18, 2011, Ms. Piccerilli had been “told how many prescriptions she could accept to be filled that day for the oxycodone and the other prescriptions. The combination [of] the [a]lprazolam and the Soma, those prescriptions.” Tr. 223–24. Ms. Piccerilli explained to Carter that, on that day, the limit had been reached by the time the customers in the waiting area had presented their prescriptions. Tr. 224.

GS Carter also asked Ms. Piccerilli to show her the prescriptions that had been accepted for filling for that day. Tr. 226. When Ms. Piccerilli showed GS Carter the prescriptions, GS Carter asked her “What is your opinion as a pharmacy technician of these prescriptions? They’re all for the same drugs, pretty much the same amounts.” Tr. 226. Ms. Piccerilli responded that “as a pharmacy, we cannot judge whether a prescription is valid. That’s up for the doctor to decide.” Tr. 226. In response to a question about whether the pharmacy filled prescriptions for out-of-state customers, Piccerilli stated that when she had started at Respondent 5195 they had “accepted prescriptions from other states, but that sometime in the last year or so, the policy had changed, and now they only accepted prescriptions for oxycodone for local customers and local doctors.” Tr. 226.

³⁶GS Carter knew that this was untrue because she had observed DEA agents counting oxycodone tablets at the time of the AIW and knew that the store was not out of stock. Tr. 221–22.

Ms. Piccerilli explained that “local” meant “somewhere around Daytona Beach or Deltona Beach to Orlando.” Tr. 226–27. It was GS Carter’s recollection that Ms. Piccerilli was cooperative throughout their encounter. Tr. 225.

Approximately an hour after her conversation with Ms. Piccerilli, GS Carter conversed with PIC Merrill behind the shelves of the pharmacy. Tr. 227. During this conversation, DI Wehrle and another DI were “in and out.” Tr. 227–28. It was Carter’s impression that Merrill was cooperative throughout the conversation. Tr. 228. In her conversation with GS Carter, PIC Merrill made the following representations:

(1) She was hired by CVS in 2009, and a few months later she was promoted to the Respondent 5195 PIC position. Tr. 228.

(2) She could fill “these oxycodone prescriptions * * * all day long, but that rather than doing that,” she, or the pharmacist on duty, sets the limit. The daily limit is determined based on “the inventory that they had on hand that morning, and also the amount of staff that they had on hand because * * * it was very time consuming * * * to call the doctors’ offices and verify each prescription.” Tr. 229–30. If a prescription could not be verified, it would not be filled. Tr. 279.

(3) When the limit fixed by the PIC was reached, subsequent customers were told that the pharmacy is out of stock.

(4) The customers were aware that the limit system is first-come-first-served, so customers would start to “stagger” in at 8:02 a.m. Tr. 230–231.

(5) If a prescription for oxycodone, alprazolam and a muscle relaxant was accepted for filling, the customer would be told to return in five hours. Tr. 230, 232.

(6) When setting the daily limit of oxycodone prescriptions, she would make sure to keep some oxycodone on hand to fill prescriptions for her “real pain patients.” Tr. 231, 232. She would dispense the prescriptions to customers she classified as other than “real pain patients” because “if she or her staff was able to confirm that a prescription had been issued by a physician who was licensed by the state, and had a DEA license, then as a pharmacy, they should be able to trust that prescription * * * is legitimate.” Tr. 234.

(7) Before filling prescriptions for oxycodone, the employees at Respondent 5195 would conduct “very stringent due diligence.” The steps taken to verify a prescription were: (i) obtain a Florida ID or a Florida driver’s license and record the number on the front of the prescription; (ii) call the prescribing physician to confirm the physician had written the prescription, whether any additional prescriptions had been issued and whether a urinalysis test had been performed; (iii) “sometimes” call other pharmacies in the area to determine whether the patient was engaging in doctor shopping; (iv) “sometimes” call a prior practitioner, if the patient’s profile³⁷ showed that a prior

³⁷GS Carter explained that “at pharmacies that * * * use[] electronic systems, there usually is a profile [that] will have the patient name and address, and it will show the prior prescriptions

practitioner had prescribed “anything” to the patient; and (v) confirm the diagnosis code, if one was absent; (vi) “sometimes” check with the state licensing boards regarding the status of the prescribing physician’s license; and (vii) use their computer system to verify the prescriber’s DEA registration. Tr. 235–36.

When looking through the prescriptions which the store had accepted for filling, GS Carter noticed that “generally” the prescriptions accepted for filling would be an oxycodone 30 mg prescription for 180 tablets, paired with a prescription for alprazolam and a prescription for Ibuprofen or carisoprodol.³⁸ Tr. 237–38. GS Carter also observed that for a particular physician, the prescriptions “appeared to be all for the same quantity and the same combination of drugs.” Tr. 239. In this regard, PIC Merrill admitted to GS Carter that she saw the patterns of prescribing in the three drugs, that she noticed that “a lot” of the customers with the cocktail were paying for their prescriptions with cash³⁹ and that “most of them” were unemployed. Tr. 238. GS Carter testified that when she suggested to Merrill that the customers may be selling their pills, Merrill simply replied “I know.” Tr. 238.

GS Carter also observed that “some” of the prescriptions which had been accepted for filling were for customers with IDs from other states but with prescriptions doctors with offices in Florida, far away from Sanford. Tr. 240. Carter recalled that this struck her as odd because “my experience has been that normally a patient will either fill a prescription by the doctor’s office or by their residence. They don’t usually stop somewhere in between.” Tr. 240. PIC Merrill had no explanation for the distances traveled by the patients to fill their prescriptions. Tr. 240.

Carter testified that following her interactions with PIC Merrill and the other members of the Respondent 5195 pharmacy team, she concluded that the general attitude was that [the Respondent 5195 pharmacy staff are] not going to question whether the prescription is valid. If the doctor says it’s valid, and they do the other verifications, then they fill it. It doesn’t matter if they all come in from the same doctor, the same way, or if they suspect that the prescription is not valid. They are going to fill it because the doctor said it was valid. Tr. 299–300.

As GS Carter was preparing to leave the store, PIC Merrill asked her whether she should fill the prescriptions which had already been accepted that day. Tr. 242–43. When GS Carter asked Merrill whether she felt that the scrips should be filled, Merrill

that they have had filled at that pharmacy. And in the case of chains, most of them show the prescriptions filled at all the other chains as well.” Tr. 237.

³⁸“The generic name of a medicinal substance used as a muscle relaxant.” 1-C Attorneys’ Dictionary of Medicine C-20783.

³⁹GS Carter testified that, while cash would be paid at the time of pickup, and thus after a determination of validity had been made, she felt that CVS’s computer system would have notified the pharmacist that previous prescriptions had been paid for with cash. Tr. 303–04.

responded that she felt she should fill them because they had been filled before. Tr. 242–43. When GS Carter pressed PIC Merrill on this issue, Ms. Lalani, who was also present, stated that none of the prescriptions would be filled. Tr. 243.

On October 28, 2011, GS Carter interviewed Paras Priyadarshi—the PIC at Respondent 219—at the DEA facility in Westland, Florida. Tr. 244–45. Also present were GS Carter, DI Wehrle, John Gilbert, Esq., and Meredith Young, Esq. Tr. 244–45. It was Carter's impression that PIC Priyadarshi appeared cooperative during the interview. Tr. 245. During their conversation, PIC Priyadarshi made the following statements:

(1) He had been employed by CVS for approximately thirteen years, and had been the PIC at Respondent 219 for approximately five years. Tr. 246.

(2) For oxycodone, alprazolam, carisoprodol prescriptions,⁴⁰ Respondent 219 would take the following verification steps: (i) examine the prescriptions for alterations; (ii) if there was no diagnosis code on a prescription, then the store would call the physician to verify the prescription. Tr. 246.

(3) If a prescription was presented with a diagnosis code by a patient who had filled at Respondent 219 before, then the store would not call the physician. Tr. 246. Similarly, if a person came in with a patient who had filled at Respondent 219 before, he would not feel the need to verify the prescription. Tr. 251.

(4) Sometime in the previous year, CVS corporate had put out guidelines that the stores should only fill prescriptions for “local” doctors and customers, and that the stores should obtain ID for all controlled substance prescriptions. Tr. 246–47. In response to this directive, Respondent 219 had stopped filling out-of-state prescriptions sometimes toward the end of 2010. Tr. 270.

(5) He found nothing odd about the fact that Respondent 219 was filling a like combination of three controlled substances (oxycodone, alprazolam, and carisoprodol), for a high number of prescribing physicians. Tr. 247–48.

(6) For Schedule II controlled substances Respondent 219 dispensed more oxycodone than any other controlled substance. For Schedule III controlled substances Respondent 219 dispensed more hydrocodone than any other substance. For Schedule IVs, Respondent 219 dispensed more alprazolam than any other controlled substance. And for non-controlled substances, Respondent 219 dispensed more Soma or carisoprodol than any other substance. Tr. 248–49.

(7) The oxycodone prescriptions would only be filled by Respondent 219 during the day shift on weekdays. Tr. 249. This was so the store could verify the prescriptions. Tr. 277.

(8) He found nothing odd about a high number of like-ailment diagnosis codes⁴¹

emanating from individual prescribers. Tr. 249–50.

(9) Customers would ask for “the Ms” or “the blues,” which were slang terms for the Mallinckrodt brand of oxycodone 30 mg tablets; but that he would not find such requests suspicious. Tr. 250, 256, 264.

(10) If a customer asked for a particular brand name, he would fill the prescription with that brand name if the pharmacy had the brand in stock. Tr. 263–64.

(11) Respondent 219 would see “a lot” of oxycodone prescriptions from Drs. Zelkowitz, Mammone, Salinas, Hannah and Pizza. Tr. 251.

(12) He would not fill prescriptions written by Dr. Pyko or Dr. Chambers because “they had prior action taken against them.” Tr. 252, 933.

That same day (October 28, 2011), GS Carter also conducted an interview with Respondent 219 Pharmacist Susan Masso. Tr. 253. As with the interview with Mr. Priyadarshi, the interview with Ms. Masso was conducted at the Westland field office, with DI Wehrle, attorneys Gilbert, and Young also present. Tr. 253. During the interview Ms. Masso made the following representations:

(1) She had been employed by Respondent 219 since June of 2011, and that for the year before that she had worked as a floater pharmacist for CVS stores in Florida. Tr. 253. Before moving to Florida she had worked as a pharmacist in New York. Tr. 253–54.

(2) Respondent 219 would verify oxycodone prescriptions by calling the physician's office and verifying the diagnosis codes. Tr. 254.

(3) She did not know why a customer who lived in one location, would travel to a second location to see a physician, and then a third location to fill the prescription. Tr. 254.

(4) Customers would request “blues.” Tr. 254.

(5) She understood that oxycodone 30 mg was for pain, oxycodone 15 mg was for “breakthrough” pain, alprazolam was for anxiety, and Soma was for muscle aches. Tr. 255.

(6) She would see oxycodone prescriptions from Dr. Pizza and Dr. Mammone. Tr. 257.

The testimony presented by GS Carter was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government also presented the testimony of DI Gayle Lane. Tr. 108–09. GS Lane testified that she has been with DEA for thirty-five years, and currently serves as a Group Supervisor at the Miami-Weston field division. Tr. 108–09.

GS Lane testified about two meetings she attended with CVS officials. She testified that she was present at the December 2010 CVS Meeting with DI Langston and CVS representative. Tr. 110. Lane also recalled that investigators from the Florida Department of Health were also present, and that “there was a discussion about the oxycodone situation in south Florida, especially in light of the new Florida state

Carter specifically mentioned the “L4, L5” code. Tr. 250.

law that doctors were limited in their dispensing.” Tr. 110–11.⁴²

On August 12, 2011, GS Lane organized a second meeting between DEA and CVS officials (August 2011 CVS Meeting). Tr. 111–12. GS Lane explained that in 2005 the Weston DEA Office “decided to interview all new pharmacy applicants and also treat all new pharmacy applications the same, and alert the chains. So when there was a new pharmacy opening up, I would contact them and they would come in for a discussion of the situation.” Tr. 111. The August 2011 CVS Meeting was conducted in response to a CVS application for a new pharmacy in Hollywood, Florida. Tr. 133. The meeting was attended by DI Lenny Levin and twenty-four CVS pharmacy supervisors, including Jennifer Lalani.⁴³ Tr. 112–13. The purpose of the meeting was to share indicators of diversion (i.e., red flags) “to help [the stores] make decisions about whether a prescription was legitimate or not, and [to address] the continued high purchases of [the Respondent Pharmacies].” Tr. 139.

Prior to the meeting, GS Lane created an outline of discussion points.⁴⁴ Tr. 113. During the meeting, she told the CVS representatives that “in the environment that we’re in it’s not enough to call the doctor to verify and also to get a picture ID.” Tr. 113. GS Lane also “cautioned * * * to be leery of Florida ID cards because they are fairly easy to get.” Tr. 113. As to the red flags⁴⁵ of diversion, GS Lane mentioned: (1) “doctors * * * writing * * * the same cocktail of drugs which was oxycodone 30 milligrams, oxycodone 15 [mg], generic Xanax 2 [mg], Soma, and * * * lately * * * a noncontrolled substance like flexural,” Tr. 114, 116.; (2) doctors without a specialty in pain management writing “large quantities” of prescriptions, Tr. 115; (3) doctors giving the same diagnosis code, “usually L–4, L–5 lower back pain,” Tr. 115; (4) patients between the ages of 25 and 40 with cash, Tr. 117; and (5) evidence of doctor shopping,⁴⁶ Tr. 118. GS Lane also identified “sponsor” arrangements in which “people from * * * mostly * * * the mountain states * * * come down in buses and vans * * * and drive to the pharmacy” to fill oxycodone prescriptions. Tr. 117–18. Under this arrangement, the driver of the van would be

⁴² The substance of this meeting has been set forth at length above.

⁴³ Ms. Lalani attended the meeting even though she was not required to because the Hollywood pharmacy was not within her area of supervision. Tr. 149–50.

⁴⁴ GS Lane did not provide a copy of the talking points to the CVS Representatives. Tr. 160.

⁴⁵ GS Lane's outline referred to “suspicious activity.” However, she testified that she would have used the term “red flag” during the meeting. Tr. 137.

⁴⁶ GS Lane explained “doctor shopping” as customers “spend[ing] their entire day trying to find doctors to write [oxycodone] prescriptions.” Tr. 118. The customers will collect multiple prescriptions at once, and then fill the prescriptions at various pharmacies. Tr. 138. During the August 2011 CVS Meeting, GS Lane told the CVS representatives that the State of Florida planned to implement a prescription drug monitoring program to combat doctor shopping. Tr. 118.

⁴⁰ DEA inquired about these three drugs “[b]ecause in looking at the prescribing records that we had obtained from CVS, we * * * observe[d] that the CVS 219 was basically filling prescriptions for the same type of cocktail prescribing pattern that CVS 5195 had been dispensing.” Tr. 247.

⁴¹ DEA had observed “that a lot of the prescriptions [had] the same diagnosis code.” GS

the “sponsor.” Tr. 118. The sponsor would normally be paid in drugs.⁴⁷ Tr. 118.

A summary Lane prepared at the request of the DEA Chief Counsel’s Office sometime after the October 2011 meeting did not contain references to the red flags that she described in her testimony. Tr. 154–156; Resp’ts Ex. 91. Also during her testimony, GS Lane explained that the red flags discussed at the meeting were “just a snapshot of what [was] going on at that time.” Tr. 161. By Lane’s account, it was her intention to provide red flag guidance to CVS “in general terms.” Tr. 161. No written list of red flags was provided to CVS by Lane at the meeting. *Id.*

Distance traveled by the customer was also identified by GS Lane as a potential red flag of diversion. Tr. 119. In particular, Lane told the CVS officials that either the doctor or the patient should be “nearby” the pharmacy. Tr. 119. GS Lane suggested that, if a pharmacist has a question regarding the distance traveled by a customer, the pharmacist should “ask why [the patient is] coming to my pharmacy.” Tr. 119. GS Lane also demonstrated how to use the Web sites of the DEA and the Florida Department of Health. Tr. 119. In this regard, she showed the CVS representatives the proper login procedures⁴⁸ for the DEA Web site, as well as the manner in which to check a doctor’s DEA registration. Tr. 121. GS Lane testified that if a registration was invalid, the DEA Web site would show the registration to be “expired.” Tr. 122–23. “If it’s a valid DEA number, [the Web site] shows the expiration date, the DEA registered location, and the schedules.” Tr. 124. She also informed the CVS representatives that the Web site was available free of charge and provided real time data.⁴⁹ Tr. 120.

When demonstrating the Florida Department of Health Web site, GS Lane “explained * * * you can click on [the] link to discipline and get all the details of what happened.” Tr. 122. GS Lane testified that she believed the Department of Health Web site was updated in real time. Tr. 122.

At the end of the August 12, 2011, meeting, GS Lane gave the CVS representatives a list of the top thirty-four CVS pharmacies that ordered oxycodone in 2010. Tr. 125–26. On the list, GS Lane specifically noted that Respondents 219 and 5195 ranked approximately 23rd and 37th, respectively, in the nation for oxycodone ordering in 2010. Tr. 127. GS Lane inquired what steps had been taken in the wake of the December meeting to address the concerns raised in that meeting regarding Respondents 219 and 5195. Tr. 128. However, since the stores were not within Lane’s area of jurisdiction, she “just asked some questions at the meeting, and that was it.” Tr. 128. At the close of the October 2011 meeting, Ms. Lalani stated that

she had looked into the stores and discovered that “one was [a] 24 hour store, and they were both very busy stores off of the I–4 corridor.” Tr. 130.

The testimony presented by GS Lane was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

The Government’s Expert

The Government presented the testimony of Professor Paul L. Doering, a retired professor of Pharmacy⁵⁰ at the University of Florida’s College of Pharmacy, who was accepted as an expert in the practice of pharmacy and the filling and dispensing of controlled substances, as it relates to the practice of pharmacy. Tr. 685. Over the course of his thirty-five-year career, Professor Doering has published many scholarly articles, and although his experience has been largely invested in research and academia, he also testified that he is a certified consulting pharmacist,⁵¹ has served as co-director of the Florida Drug Information and Pharmacy Resource Center, and that he had some limited, part-time experience as a practicing pharmacist while in graduate school at the nascent stages of his career.⁵² Tr. 667, 673, 678, 682. He testified that he has presented expert testimony approximately seventy-five times; having been presented as a witness for the Government on every occasion. Tr. 794.

Professor Doering testified that, when presented with a prescription for a medication, a pharmacist’s [p]rofessional responsibilities include reviewing that prescription to see whether or not the doses are appropriate for that patient, looking at other medications that individual may be taking to see whether there’s interactions. If there are problems, phoning the prescriber or other individual to resolve those problems, [] in a nutshell, certifying that that prescription is ready for transfer from the possession of the pharmacist to the ultimate end user [and counseling] the ultimate end user . . . about any information that might be necessary for the safe and effective use of that drug.

Tr. 690. Doering further explained that controlled substances fall within a category of what he terms “high alert drugs,” where there is an enhanced potential for problems stemming from incorrect use. Tr. 691. Special care, in Doering’s view, must be exercised by a pharmacist dispensing high alert drugs, and particular scrutiny must be leveled at opioids, benzodiazepines, and barbiturates. Tr. 690–92. Although Professor Doering consistently presented his testimony in terms of how *he* would exercise *his* professional judgment, he made it clear that in his opinion, he was presenting the standard for pharmacy registrants in Florida, in his words, “[i]t’s what they’re taught in school.” Tr. 758.

Professor Doering testified that there are there are circumstances surrounding the

presentation of a prescription to a pharmacist, i.e., “red flags,” that can create an obligation on the part of a reasonable pharmacist to decline to fill, or to take other action in the exercise of the pharmacist’s professional judgment. Tr. 693–97. According to Professor Doering, red flags create in a pharmacist the obligation to assure him or herself that the presented prescription may be filled properly. Tr. 843. In Doering’s view, the steps taken to address a red flag necessarily are dependent upon the nature of the concern raised by that flag, and are not amenable to the mechanical application of a fixed checklist. Tr. 697–98. For example, requiring identification from the presenter of the scrip can be utilized to ensure that the presenter of the scrip is who he or she claims to be, and can also facilitate the re-contacting of the person if necessary. *Id.* In a similar fashion, contacting the prescriber who drafted the scrip can be helpful in resolving some red flags, but where the red flag (or flags) suggests that the prescriber is “working collaboratively with patients to divert drugs,” contacting that physician provides no real assurance of the *bona fides* of the prescription. Tr. 699. Professor Doering indicated that a practice has developed among pharmacists to contact the prescriber in an attempt by some in the profession to create a form of contrived, unfounded absolution for inadequate controlled substance dispensing. In Doering’s words, “over the years there has been a perceived value to the pharmacist that [‘]it’s out of my hands because I called and I got some voice on the other end that said yeah, that’s a good scrip.[’] But it’s my firm opinion * * * that’s inadequate to verify the authenticity or appropriateness of that prescription.” Tr. 699–701. Professor Doering acknowledged that Section 64B of the Florida Administrative Code contains some applicable standards, but testified that this provision is not an exhaustive compilation, and that “[t]he standards of care . . . are not always determined by law, by statute, by rule. They’re determined, in fact, by what pharmacists do under like, or similar circumstances.” Tr. 921.

Doering also testified that in exercising independent dispensing judgment, the pharmacist will consider and compare the address of the patient on the scrip and the address of the prescriber who drafted it. Tr. 702.

The method of payment is also, in Doering’s opinion, a potential red flag of diversion. According to Doering, “typically, people who may be diverting or otherwise misusing their drugs will pay cash.” Tr. 703. However, Professor Doering conceded that standing alone, the fact that a controlled substance prescription was purchased in cash would have “very little” impact on the decision by a reasonable pharmacist to dispense or decline to dispense. Tr. 705.

Another red flag proposed by Professor Doering is the observation, by a pharmacist, that a particular prescriber is writing “in a factory-like manner, prescriptions for the same drugs, the same quantities . . . without any kind of variability or change considering the different patients that come into that pharmacy.” Tr. 708.

⁴⁷ GS Lane was not aware of any instances where either of the Respondent Pharmacies filled prescriptions for these “sponsor” groups. Tr. 139.

⁴⁸ To log into the DEA Web site, a registrant needs their registration and tax ID information associated with their DEA registration. Tr. 123.

⁴⁹ Though GS Lane recommended that CVS use the DEA Web site, she conceded that it was “not uncommon” for large chains to use third-party systems for checking registrations. Tr. 147.

⁵⁰ Professor Doering testified that he is a “distinguished service professor emeritus.” Tr. 662.

⁵¹ Professor Doering testified that he has served as a consultant pharmacist at a penal institution. Tr. 684.

⁵² Professor Doering’s CV was received into the record without objection. Gov’t Ex. 6; Tr. 666.

Over the course of his testimony, Professor Doering was asked about individual and groups of dispensing events presented on spreadsheets⁵³ that were derived from dispensing data furnished to the DEA by the Respondents. For example, Professor Doering discussed eight controlled substance dispensing events that took place on August 16, 2010, at Respondent 219. Gov't Ex. 57 at 33; Tr. 710–23. Doering testified that the data reflected numerous shared red flags for the eight events, to include that cash was the method of payment, like varieties and strengths of medications were dispensed for all but one patient, all medications were dispensed to patients where an out-of-Florida address was provided, and the common prescriber for all eight patients had a listed practice address in Fort Lauderdale, Florida. Tr. 722–23. In Professor Doering's expert opinion, the combination of these red flags in these prescriptions would not be resolvable to a point where a reasonable pharmacist, exercising his or her corresponding responsibility, could dispense the prescribed controlled substances. *Id.* In explaining his conclusion, Doering reiterated his misgivings regarding the efficacy of a pharmacist limiting the inquiry to checking patient identification and telephonic communication with the prescriber (common to all eight patients), who, by his estimation, in view of the nature of the transactions, were likely complicit in diversion. *Id.*

Professor Doering made like observations and a like conclusion regarding the resolvability of four similar controlled substance dispensing events which occurred on September 24, 2010, at Respondent 219. Gov't Ex. 57 at 33; Tr. 723–25. Doering concluded that the confluence of these out-of-Florida patients on a single day receiving the same medications in the same quantities from the same in-Florida prescriber, was “highly, highly unlikely.” Tr. 725. Based on this conclusion, Professor Doering testified that, he is “simply not going to fill those prescriptions,” and that nothing could be presented in a hard copy of the prescription scrips that could alter his opinion on the matter with respect to either the August 16 or September 24 dispensing events. Tr. 739–41.

According to Professor Doering, four dispensing events at Respondent 219 which occurred between August 29–30, 2010, presented similarly unresolvable red flags. Gov't Ex. 57 at 15; Tr. 752–58. Doering testified that “it's the conflagration or a combination of things that suggest to me that these prescriptions were not issued in the usual course of medical practice.” Tr. 757–58. Similar testimony was elicited regarding four controlled dispensing events regarding the same Respondent (219) on August 19,

2010. Gov't Ex. 57 at 38; Tr. 759–64. Again, these red flags, in Doering's view, were not resolvable when examined collectively. Tr. 763–64.

Additional dispensing events which occurred at Respondent 219 on August 16, 2010, were also addressed by Professor Doering. Tr. 917–20; Gov't Ex. 57 at 33. Of eight oxycodone 30 mg prescriptions dispensed that date issued by a particular Fort Lauderdale physician, only two had patient addresses in Florida. Tr. 919–20. Doering testified that a reasonable and prudent pharmacist would need to resolve this anomaly prior to filling the prescriptions. Tr. 920.

In similar fashion, Professor Doering addressed four controlled substance dispensing events that occurred at Respondent 5195 on August 26, 2010. Gov't Ex. 57 at 29; Tr. 741–51. Doering found unresolvable red flags based upon the combination of the cash-discount⁵⁴ method of payments, the out-of-Florida addresses of the presenting patients, the distance between the patients' home addresses and the Pompano Beach, Florida prescriber, the “high alert” nature of the dispensed controlled substances, and the close sequential nature of the transaction numbers, which suggested to him that the medications were dispensed in close temporal proximity.⁵⁵ Tr. 751. Like red flags, which according to Professor Doering, presented unresolvable impediments to dispensing within the standard, were identified regarding six (6) controlled-substance dispensing events which occurred at Respondent 5195 on August 11, 2010, regarding prescriptions emanating from the same West Palm Beach, Florida prescriber. Gov't Ex. 57 at 35; Tr. 764–76. Doering testified that the West Palm Beach provider is “roughly” 200 miles from Respondent 5195. Tr. 915. Among that group, Professor Doering testified that two of the patients, who had the same last name, lived in the same out-of-Florida address,⁵⁶ and received

the same quantity of the same controlled substances from the same Pompano Beach physician, were sufficiently questionable that he characterized the confluence of red flags as “an attention getter.” Tr. 776. Doering characterized the aggregate of the red flags present as not amenable to sufficient resolution to warrant dispensing. Tr. 916.

Professor Doering also highlighted prescribing red flags relative to medications dispensed to four patients on prescriptions issued by one Longwood, Florida physician on December 23, 2010. On that date, at each of the two Respondent pharmacies, two patients were provided identical quantities of oxycodone 30 mg, oxycodone 15 mg, and alprazolam 2 mg. Stated differently, all four patients received exactly the same quantities of the same medications in the same strength. Gov't Ex. 55 at 15, 47 (Respondent 219) and 62, 74 (Respondent 5195); Tr. 784–86. Professor Doering explained the red flags he identified as follows:

Well, from a clinical pharmacist perspective that combination of drugs is what I would call a red flag because alprazolam and oxycodone are commonly diverted to nonmedical use. It also, from my perspective, makes no sense at all that there would be two prescriptions for oxycodone, one in a 15 milligram strength and the other in a 30 milligram. Now one might speculate that the reason for that is that pain can vary throughout the day and it may be that the individual is suggested to take the 15 [mg] when the pain is not so great and the 30 [mg] when it is so great. But 30 milligram tablets are scored right down the middle, and it's quite easy to break them in half. It just doesn't make any sense to me why there would be two prescriptions.

Tr. 784. According to Doering, pill cutters are now commonly sold at pharmacies. Tr. 786–87. Professor Doering testified that the similarity in quantity and combination of medications “would suggest that the one size fits all concept was in the mind of [the prescriber] when he was prescribing. It's just highly suspicious when you see the same drugs, the same quantities, the same patterns over and over again.” Tr. 784–85. Professor Doering referred to this phenomenon as “pattern prescribing,” which he defined as the presence of an “unwavering combination of the same drugs in the same strengths in the same quantities across numerous patients.” Tr. 923. Doering classified pattern prescribing as an unresolvable red flag. *Id.* According to Professor Doering, a pharmacist would not need a print-out for such patterns to become apparent. Tr. 927. Regarding the simultaneous prescribing of two strengths of oxycodone (30 mg and 15 mg), Doering explained:

[T]he sale of drugs on the street doesn't follow supply-side economics. It's sort of get what you can when you can. It's quite common for people to obtain as much of the types of drugs that they might intend to use themselves or sell to other people[.]. It just doesn't make sense to me, these combinations.

Tr. 890.

Professor Doering was also asked to evaluate the same three controlled substance

⁵³ On January 9, 2012, Professor Doering received the spreadsheets from the DEA Investigator Hamilton. Tr. 799. At this time, Investigator Hamilton explained to Professor Doering how to access each file and what the data in the file represented. Tr. 800. Professor Doering spent approximately twelve to fourteen hours with the spreadsheets. Tr. 812. One spreadsheet, Government Exhibit 22, was sent to Professor Doering with the highlights reflected in the exhibit. Tr. 809–10.

⁵⁴ As discussed, *infra*, Joseph Abbott, CVS Vice President of Pharmacy Operations, testified that “cash discount” on the CVS-furnished spreadsheets denotes that, although, like the “cash” designation, full payment was made at the time of the transaction, some manner of group discount (e.g., AARP) was utilized at the time of payment and these transactions may include both cash and credit card payments. Tr. 1234–35. It seems clear from the record that these are transactions where the customers did *not* have the benefit of health insurance assistance. Professor Doering conceded that if “cash discount” merely denoted that the patients utilized an AAA discount at the time of purchase that this aspect would lose its potency as a red flag. Tr. 847. However, according to Professor Doering, even if the “cash discount” red flag aspect were eliminated from the equation, the remaining red flags are still unresolvable. Tr. 924–25.

⁵⁵ Professor Doering did concede, however, that he was not aware at what point a prescription number is assigned to a dispensing event at CVS stores. Tr. 832–33, 876, but testified that he “would bet a dime to a Dunkin' Donut that [the events with close prescription numbers] were presented in proximity to one another * * *.” *Id.* at 926–27.

⁵⁶ Professor Doering testified that the single in-Florida oxycodone dispensing event entry on that day reflected a patient address in Pompano Beach, Florida, over 200 miles from Respondent 5195. Tr. 915–16.

medications (oxycodone, oxycodone, and alprazolam) that were dispensed in the same quantities (30 mg, 15, mg, and 2 mg) to four out-of-area patients on January 6, 2011 at Respondent 219. Tr. 787–792; Gov’t Ex. 55 at 13, 22, 31, 51. Doering provided the following evaluation of the red flags these dispensing events presented to him:

Well, in several instances here there is a great distance between the prescriber and the patient, and the pharmacy is sort of in what I would call an illogical place. I don’t think it’s a secret [that] there are CVS/Pharmacies all over this nation, and one of the things I did in analyzing this was to look using Google Maps where these people lived, where the doctors were, and where the pharmacies are. It just didn’t make sense to me. People are traveling all over creation with gas at nearly \$4 a gallon to get a prescription filled in a place that’s not near their home [and] it suggests to me that people are driving to these specific pharmacies because they know that they can get these prescriptions filled.

Tr. 791–92. Doering explained that a pharmacist examines multiple red flags collectively,⁵⁷ and testified that, in his opinion, contacting the prescribing physician and/or obtaining a diagnosis code would not resolve these red flags to a degree where the medications should have been dispensed. Tr. 792–93. Doering agreed that he did not know what measures, if any, the Respondents’ pharmacists took to resolve any conflicts, or whether a patient history screen was consulted prior to the dispensing event. Tr. 868, 873. When pressed on whether the distance red flags were potentially explainable under various hypothetical scenarios involving vacation and travel, Doering had this to say:

The kinds of medications that we’re talking about here are for chronic health problems and not acute health problems. So, it would be unlikely that someone comes to Florida on vacation, breaks a leg, and has to get oxycodone in these quantities and in these strengths. So it just doesn’t add up. Tr. 854.

With regard to the resolution of red flags, Professor Doering testified that “it’s customary that pharmacists make a notation” when resolving red flags. Tr. 773. However, Doering allowed that “in today’s computer age I do not know whether CVS’ system allows for memorialization of that type of thing, but historically it’s been written by hand, usually on the back of the prescription.” Tr. 773.

The Respondents contend that Professor Doering’s expert testimony should be excluded or, in the alternative, given little or no weight. In support of these arguments, the Respondents contend that Professor Doering’s opinions are not based on a reliable methodology, as defined by *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579, 592–93 (1993), and are the product of bias. Resp’ts Brief, at 92–96.

As an initial matter, Courts of Appeals are split on the application of *Daubert* to administrative proceedings such as these.

The Third and Ninth Circuit Court of Appeals have held that, insofar as *Daubert* “rests on an interpretation of Federal Rule of Evidence 702,” where an agency has not adopted the Federal Rules of Evidence, the rules of *Daubert* will not apply. See *Bayliss v. Barnhart*, 427 F.3d 1211, 1218 n.4 (9th Cir. 2005); see also *National Taxpayers Union v. U.S. Social Sec. Admin.*, 302 Fed. Appx. 115, 121 (3rd Cir. 2008). In contrast, the Seventh and Federal Circuits have applied variations of the *Daubert* inquiry to administrative hearings. See *Pasha v. Gonzales*, 433 F.3d 530, 535 (7th Cir. 2005) (applying “spirit of *Daubert*” to administrative hearing); see also *Libas, Ltd. v. U.S.*, 193 F.3d 1361, 1366 (Fed. Cir. 1999) (*Daubert* factors should be used to determine the reliability and proper weight to be assigned to expert testimony at administrative hearings.).

While the Federal Rules of Evidence “do not apply directly to these proceedings” they “may be used for guidance where they do not conflict with agency regulations.” *Rosalind A. Cropper, M.D.*, 66 FR 41040, 41041 (2001) (citing *Sinatra v. Heckler*, 566 F.Supp. 1354, 1358 (E.D.N.Y. 1983)). In this vein, the Agency has held that unreliable expert testimony cannot constitute substantial evidence. *Hilmes Distributing, Inc.*, 75 FR 49951, 49954 (2010). Because the reliability of expert testimony is a relevant consideration under Agency precedent, *id.*, and because the *Daubert* test is used to determine the reliability of expert testimony, the *Daubert* test provides appropriate guidance for evaluating the reliability of Professor Doering’s testimony. *Id.*

Under *Daubert*, “expert testimony is admissible if (1) the expert is qualified to testify competently, (2) the expert has used sufficiently reliable methodology in reaching a conclusion, and (3) the testimony will assist the trier of fact.” *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1312 (11th Cir. 2000). The first and third prongs of the test are not at issue here: Professor Doering was correctly received as an expert without objection at the hearing, and his testimony addresses the heart of what must be determined in this recommended decision. With regard to the reliability prong, the Supreme Court has provided a list of non-exhaustive factors which a tribunal may consider when evaluating an expert’s methodology. *Daubert*, 509 U.S. at 593–94. However, “district courts need not adhere to those enumerated factors, as the inquiry is a flexible one.” *Surles ex rel. Johnson v. Greyhound Lines, Inc.*, 474 F.3d 288, 295 (6th Cir. 2007) (internal punctuation omitted). Indeed, “where non-scientific expert testimony is involved the *Daubert* factors may be pertinent or the relevant reliability concerns may focus upon personal knowledge or experience.” *Id.* (internal punctuation omitted) (emphasis supplied).

Here, Professor Doering’s testimony concerned the application of the standard of care regarding the filling of controlled substance prescriptions in the face of red flags. Such testimony is more akin to “technical or other specialized” knowledge than it is to the “scientific” testimony which was the subject of *Daubert*. *Surles ex rel. Johnson*, 474 F.3d at 296. Accordingly,

Professor Doering’s knowledge and experience, rather than the specific *Daubert* factors, provide the appropriate analytical framework for evaluating the reliability of his opinion. *Id.*

Professor Doering testified that he has been a professor of pharmacy for thirty-five years and that, in this capacity, he has taught classes on controlled substance diversion within the practice of pharmacy. Tr. 662–71. Simply put, Professor Doering has sufficient knowledge and experience to render sufficiently reliable his opinion on the subject of the existence and resolvability of red flags of diversion.

The Respondents also contend that Professor Doering’s history of testifying for the Government and “long standing relationship with the DEA”⁵⁸ and willingness to be its on-call expert undermine[] his claim to be an expert.” Resp’ts Brief, at 94–95. Interestingly, as discussed, *infra*, the Respondents’ expert (who they propound as the superior source of impartial expert assistance) testified that he has only testified as a witness on behalf of the defense. While Professor Doering’s relationship with the DEA and his history of Government testifying were extensively explored by counsel during voir dire at the hearing, and are certainly relevant considerations in evaluating the weight to be assigned to his testimony, he credibly testified that it is his practice to conduct an independent review of records, to “formulate opinions and if those opinions were favorable to the DEA’s position” to serve as a witness. Tr. 797. Under these circumstances, Professor Doering’s testimony was sufficiently credible and persuasive to constitute substantial evidence in these proceedings.

The Respondents’ Evidence

The Respondent’s presented the testimony of their own expert witness, a statistician, as well as the testimony of the CVS vice president of pharmacy operations.

The Respondents’ Expert Witness

The Respondents presented the testimony of Professor David Brushwood. Like the Government’s expert, Professor Brushwood is employed⁵⁹ at the University of Florida as a Professor in the College of Pharmacy.⁶⁰ Tr. 1003. Also like the Government’s expert, Professor Brushwood is widely published, and has concentrated the majority of his professional pharmacy experience in academia and research, with an early stint as a part-time pharmacist.⁶¹ Tr. 1003–06. He also holds a law degree and has taught numerous classes on the intersection of law and pharmacy. Tr. 1003–04, 1008. Professor

⁵⁸ Professor Doering testified that he has an arrangement with the DEA under which he is “willing to review records and formulate opinions and if those opinions [are] favorable to the DEA’s position tha[n] I would be available [to serve as an expert].” Tr. 797.

⁵⁹ Professor Brushwood testified that he is currently on a sabbatical leave.

⁶⁰ Professor Brushwood’s CV was received into evidence. Resp’t Ex. 1.

⁶¹ Although he no longer practices as a pharmacist, Professor Brushwood holds an active pharmacy license in the State of Kansas. Tr. 1004.

⁵⁷ Tr. 924.

Brushwood testified that he has testified as an expert witness on five occasions, always for the defense. Tr. 1009–10. He was received without objection as an expert in pharmacy and the pharmacist's responsibilities for the dispensing of controlled substances. Tr. 1010–11.

Professor Brushwood acknowledged that prescription drug abuse in Florida has reached epidemic proportions. Tr. 1014–16. To address this problem, a pharmacist must “ensure that controlled substances continue to be available for legitimate medical and scientific purposes while preventing diversion into the illicit market.” Tr. 1053. Citing Appendix D of the *DEA Pharmacist's Manual*,⁶² Brushwood refers to this concept as the principle of balance. Tr. 1053. Professor Brushwood interprets the pharmacist's corresponding responsibility in this way:

[O]ur corresponding responsibility is not the same as the prescriber's responsibility. As pharmacists, we have certain knowledge and skill and abilities that are very important and we are to exercise all of that that we have, but it's not the same as what prescribers have. It's their responsibility not to issue a prescription that isn't for a legitimate medical purpose and isn't in the usual course of professional practice. It's our corresponding responsibility to, based on the knowledge of drugs that we have, apply our expertise. If we recognize or have a concern then we stop and say wait a minute. I need to think this through. Maybe I need some additional information, and until I am satisfied that I can fill this prescription and meet my responsibility I'm not going to do it.

Tr. 1024–25. Brushwood clarified that pharmacists “don't see ourselves as the police of the medical profession [but rather] people who evaluate prescriptions and apply our expertise.” Tr. 1106. When asked to define a controlled substance red flag, Professor Brushwood testified that:

A red flag means stop. This is the way I define it. A red flag means stop, think, look, examine the circumstances, use what you have available to you—it doesn't take long necessarily—and make a decision. Go forward only after you have had this opportunity for information gathering and reflection and do it only when it's safe. The result of analysis of a red flag will either be to fill a prescription or to not fill a prescription. Those are the only two possible results, and you don't do that if there is a red flag without this introspective activity.

Tr. 1034. Professor Brushwood refers to a red flag that is correctly resolved by a pharmacist in favor of dispensing as a “red herring.” Tr. 1035. He testified that, in addition to discussions with patients and prescribers, pharmacists may consider past history with the patients as customers, visual cues (e.g., crutches), and patient profiles maintained at the pharmacy. Tr. 1034–36, 1073–74.

Professor Brushwood testified that he has created a mnemonic, “VIGIL,” that he uses to teach a standardized approach to

executing the pharmacist's corresponding responsibility. Tr. 1021. The “V” in the mnemonic is for “verification.” This is to remind the pharmacist to contact the prescriber's office to the extent needed to “at least assure yourself that the prescription was issued by the prescriber and, if necessary, engage in additional discussion with them.” Tr. 1027. It is Brushwood's view that this step should always be taken with a certain level of circumspection. He explained his basis for this level of circumspection in this way:

We want to be very economical with our contacts with prescribers' offices because they become irritated when we call them for no good reason. We want them to understand that we're important and we're not bothering them with trivia, so if we don't need to contact them because we've previously verified we don't do it again.

Tr. 1028. Elaborating on the point, Professor Brushwood explained:

Well, we don't want to cry wolf, and I think annoyance is a factor. We want them to take us very seriously, and when they get a call from us they know that we really need them so they pay attention to us. If [the prescribers] become accustomed to the idea that we're calling simply to reconfirm something we already know their perspective is we need to use our professional judgment, not simply defer to them and their professional judgment.

Id.

The “I” in Brushwood's VIGIL model stands for “identification.” Tr. 1021, 1030. This reminds the pharmacist to seek a government-issued identification from the individual presenting the prescription scrip. Tr. 1030. The “G” refers to “generalization,” which suggests to the pharmacist that he and the dispensing patients “reach an agreement” regarding their mutual responsibilities as pharmacist and patient.⁶³ Tr. 1031. The second “I” in VIGIL stands for “interpretation,” which is the process of tallying a set of points assigned to the other aspects of the VIGIL model in analyzing a dispensing decision. Tr. 1031–32. The details of the “I” point system or how they are assigned were never explained during the hearing. The “L” stands for “legalization,” which, according to Professor Brushwood, is a caution against pharmacists' historical “well-intended tradition to occasionally bend a rule or two * * *.” Tr. 1032.

Reduced to its essence, Professor Brushwood's VIGIL model really contains only two steps to resolve a red flag presented at the time of a scrip presentation: contacting the prescriber (“V” or “verification”), and checking the identity of the presenter (“I” or “identification”). The three remaining parts of the model, including the point or “interpretation” (“I”) aspect of the model that was never explained, the “generalization” (“G”) portion, which is (even by Brushwood's own estimation) never used by pharmacists, and the “legalization” (“L”) part which is a reminder to abide the

law, all relate to policy approaches, not red flag resolution.

Regarding red flag resolution, like the Government's expert, Professor Brushwood acknowledged the requirements of Section 64B in the Florida Administrative Code, provided his opinion that the Respondents' policies and dispensing protocols meet the requirements therein,⁶⁴ but (like Professor Doering) conceded that the text of Section 64B did not provide an exhaustive list of red flags. Tr. 1091. In this regard, Professor Brushwood testified that “much of [the Florida standards of pharmacy] simply reiterates language from Federal law.” Tr. 1208. By Professor Brushwood's estimation:

Pharmacists have to use their best professional judgment at all times, and although not formally stated here * * * pharmacists still have to use their professional judgment, which may go beyond these five [64B] factors.

Tr. 1049–50.

Consistent with the *DEA Pharmacist's Manual* (as well as the view of the Government's expert), Professor Brushwood agreed that the quantity of drugs prescribed and the frequency of prescriptions filled may be non-dispositive indications of fraud or improper prescribing. Tr. 1056–58, 1062–65. Brushwood stated:

I would never teach that a ridiculous outlier high is of no significance in and of itself. I would teach that it is. You better investigate when you see that I would teach a pharmacist.

Tr. 1058. It is Professor Brushwood's opinion, however, that a pharmacist would only be able to see trends in dispensing for a particular patient, rather than for a particular prescriber or multiple patients. Tr. 1069.

An evaluation of Professor Brushwood's testimony demonstrates that he shares many of the views expressed by the Government's expert in many respects. He agreed that a combination of 56 dosage units of oxycodone 15mg, 168 dosage units of oxycodone 30 mg, and 56 dosage units of alprazolam 2 mg did, presented a red flag,⁶⁵ but (unlike the Government expert) felt the red flag could be resolved. Tr. 1081–82, 1203–04, 1212. Although opining that physicians are often creatures of habit who frequently stick with historically successful combinations of medications,⁶⁶ he concurred that multiple patients from a single prescriber on a single day with the same combination would also be a red flag. Tr. 1093, 1098, 1119, 1168, 1170. He also agreed that oxycodone and alprazolam are medications with a high risk of abuse and diversion. Tr. 1086. Furthermore, he agreed that prescriptions written by local prescribers for out-of-state patients constitute a red flag requiring resolution, that contacting the prescriber will not always be sufficient to resolve every red flag, and that there can be a point where a pharmacist should cease to fill scrips emanating from a particular prescriber based on diversion concerns. Tr. 1119–20, 1124,

⁶² A copy of which was received into evidence. Resp't Ex. 19.

⁶³ Professor Brushwood testified that no pharmacy utilizes this aspect of his VIGIL model. Tr. 1031.

⁶⁴ Tr. 1084.

⁶⁵ Tr. 1081.

⁶⁶ Tr. 1174, 1205–06.

1148. He concurred in the principle that distance can be a red flag,⁶⁷ and testified that the Sanford area was a “reasonable geographic area” for the Respondents’ pharmacies (but added the proviso that travelers in need of medication should not go without when in the Sanford area), and conceded that he did not come across a handwritten scrip note addressing any distance red flag in the materials he reviewed for the Respondents. Tr. 1139, 1145, 1166. Brushwood agreed that the prescription events presented to the Government’s expert contained multiple cognizable red flags in need of pre-dispensing resolution. Gov’t Ex. 57; Tr. 1142–50, 1155–60, 1189.

Areas of mutual accord notwithstanding, Professor Brushwood did not agree with the ultimate conclusion of the Government’s expert that the dispensing patterns evident in the reviewed data demonstrate that the controlled substance prescriptions were not issued for a legitimate medical purpose in the usual course of a professional practice, or that the red flags present were unresolvable. Tr. 1068, 1199. Employing a number of double negatives, Brushwood explained his opinion in the following way:

Based on the information I’ve reviewed, I am not able to conclude that [the Respondents’ pharmacists] didn’t meet their corresponding responsibility. [This is based upon examination of] their policies and procedures, which in my opinion accurately describe the pharmacist’s corresponding responsibility. I have looked at the declaration of [Pharmacists Masso and Merrill] * * * which under oath indicate that they have followed those policies. I have looked at some information that shows me that contact was made with the prescriber’s office for verification of prescriptions, that identification was obtained for patients for prescriptions. What I don’t know is the relationship that the pharmacists had with the patients. I don’t know the patient profile that was available to the pharmacists at the time these prescriptions were filled. I don’t know what history they had had with the patients or really what the nature of the conversation they had with the prescribers was, if there was a conversation, or the conversation they had with the patients. There’s a lot of aspects of the investigation or the consideration of responsibility that is unavailable to me.

Tr. 1067.

In other words, Professor Brushwood opined that, without the patient profiles and other information, it is impossible to know whether the pharmacies violated their corresponding responsibilities. Tr. 1075, 1199–1200. As a preliminary matter, the affidavits of Masso and Merrill that were referenced among the items which formed his expert opinion were not offered or received into evidence. While an expert is entitled to rely on facts not in evidence when developing his opinion, such reliance does not relieve the proponent of the expert’s testimony from establishing the facts on which the expert relied. *See TK-7 Corp. v. Estate of Barbouti*, 993 F.2d 722, 732 (10th

Cir. 1993) (“The fact that [the expert] relied upon [a] report in performing his calculation of lost profits did not relieve the plaintiffs from their burden of proving the underlying assumptions contained in the report.”).

Furthermore, although Professor Brushwood went on to explain that he could not draw a conclusion about whether the Respondents’ pharmacists had met their obligations absent the additional types of information he listed, which he characterized as “pretty rich,”⁶⁸ the only information his VIGIL model requires the pharmacist to gather and evaluate is verification (“V”) and identification (“I”).

Paradoxically, although Professor Brushwood placed so much emphasis on the extent to which his evaluation was hobbled by his inability to examine items such as any entries in the patient profile maintained by the Respondents, he revealed that he believed the information would have been available upon request, but that he did not ask to see it. Tr. 1073–74.⁶⁹ The record contains no reason to question Brushwood’s belief that he could have had access to the patient profiles upon request. If the profile was accessible to him and as vital as he claimed, it would make little sense for him not to have asked to review it. Yet he testified that he never asked. In view of his impressive credentials and experience, and the fervor in which he presented his view that the profile information is key, it is unlikely that his failure to request the profile information is based upon a blunder or an oversight. To be clear, the operative fact is not that the Respondents elected not to provide the information at the hearing, but rather, that Brushwood emphatically declared how vital it was, and conceded that he never even asked the Respondents for it—but could have had it upon a mere request. Here it is not imperative to determine whether the information in the profile would have been unhelpful to the Respondents or whether a review of the information is truly a condition precedent to an accurate assessment of the pharmacists’ actions. On the present record, that portion of Brushwood’s testimony that urges the crucial impact of patient profiles and what they might have demonstrated has been sufficiently neutralized that it neither favors nor disfavors any material issue to be decided in the case.

The only documented actions aimed at red flag resolution that Professor Brushwood described seeing in the materials he reviewed on behalf of the Respondents were notations on numerous prescription scrips he examined in the course of his review. Tr. 1069–70. Brushwood testified that, although the practice among the profession has been uneven, handwritten notes by a pharmacist on a scrip indicate that there has been communication between the pharmacist and/or the prescriber. Tr. 1070–71, 1160–61. Further, with respect to Schedule II prescriptions (such as those examined in the data in this case), Professor Brushwood testified that a handwritten note on the scrip

“is certainly one place where you would expect to see [such notes].”⁷⁰ Tr. 1072.

Professor Brushwood disagreed with the Government expert’s conclusion that a 210 dose prescription for oxycodone 30 mg was a red flag because of the dosage. Tr. 1076–77. However, the probative value of this inquiry was profoundly undermined by form of the question, which omitted the other red flags identified by the Government expert that were factored into his answer. The Government expert testified that the nature and doses of the medication dispensed to remotely located patients and prescribers were unresolvable because the combinations were consistent with chronic pain, and not acute pain symptoms resulting from accidents while on vacation. Tr. 854. Thus, it was not the dose alone that the Government’s expert declared unresolvable, but the confluence of elements attendant on the schedule II dispensing event.

Professor Brushwood presented as a knowledgeable, prepared, and helpful witness. That said, the persuasiveness of his testimony was undermined appreciably by his repeated assurances that the identified red flags could have been resolved by reviewing the entries in the patient profiles that the Respondents maintained and that Brushwood never asked to see. Although Professor Brushwood suggested that there were other areas that could have been explored to resolve conflicts, his VIGIL model only identified checking the identity of the patient and contacting the prescriber and/or the presenter, avenues which he ultimately agreed would not have resolved red flags associated with prescribers who were complicit in diversion. No alternative route beyond the patient profile information, prescriber/patient communication, and/or identification verification were proposed by Professor Brushwood. Accordingly, notwithstanding his sincere efforts and credible testimony, his presentation was less helpful than the testimony presented by the Government’s expert witness.

The Respondents’ Fact Witnesses

The Respondents presented the testimony of Paul Greenberg, the Director of the Health Economics Practice at Analysis Group,⁷¹ “an economic research and consulting firm in Boston.” Tr. 948, 948. Mr. Greenberg holds an undergraduate degree in economics from Vassar College, a master’s degree in Economics from the University of Western Ontario, and an MBA from the Sloan School

⁶⁷ Indeed, Respondent 219 Pharmacist Technician Keyla Perry indicated that such was the practice, Tr. 345, and the Respondents’ own dispensing guidelines for pain management that were in effect no later than December of 2010 required the pharmacist to “[d]ocument communications with prescriber or agent on the back of the prescription to include date, time, outcome and name of person.” Resp’t Ex. 23 at 2. Thus, there is no question that after December of 2010, Respondents’ pharmacists were under a duty to document such communications on the back of the prescription scrips.

⁷¹ Mr. Greenberg explained that Analysis Group Inc., (“AGI”) “is a consulting firm headquartered in Boston, with 10 offices around the country, and one in Montreal, Canada.” Tr. 949.

⁶⁸ Tr. 1067–68.

⁶⁹ When asked if he could have seen the profile, Brushwood declared “I’m sure I could have.” Tr. 1073.

⁶⁷ Tr. 1181, 1194.

of Management at the Massachusetts Institute of Technology.⁷² Tr. 945–46; Resp'ts Ex. 2.

Mr. Greenberg testified that he is often involved in litigation “involving the use of data in one form or another.” Tr. 948. In this regard, Mr. Greenberg explained that his “work is really applied economics and statistics in a consulting capacity. We get hired by a variety of clients in the healthcare sector [to perform] analysis of large data sets in which we apply our economics and statistics training to study, examine, and glean insights from those data.” Tr. 947–48.

Greenberg testified that he was asked by CVS to “study * * * some of the data surrounding some prescribers who had * * * recently been suspended by CVS, specifically with an eye to the dispensing patterns that were occurring at [Respondents] 219 and 5195.” Tr. 950. Though the dispensing data was the “core” data used in Mr. Greenberg’s analysis, he also looked at information provided regarding CVS Extra Care Cards. Tr. 952. Mr. Greenberg testified that his work on the case could be grouped in the following manner: (1) “proximity analysis,” which looked at the proximity of prescribers and patients to the Respondent Pharmacies; (2) “the nature of the transactions and the methods of payment for those transactions;” and (3) “patterns of dispensing at [the two pharmacies] based on the kinds of drugs that were dispensed.” Tr. 952–53.

When looking at the geographic proximity of the prescribers, Mr. Greenberg testified that he looked at the CVS dispensing data and focused on the top 100 prescribers of oxycodone for the Respondent pharmacies. Tr. 954. Based on this data, Greenberg created a map which shows the location of Respondent 5195—marked with a red dot—relative to the locations of the top 100 oxycodone prescribers for the period of March 2010 to February 2012—marked with blue dots. Tr. 955–56. The map was admitted into evidence as Respondents’ Exhibit 88. Tr. 961. Mr. Greenberg testified that he created a similar map showing the location of Respondent 5195 relative to the top 100 oxycodone prescribers for the period of January 2011 to February 2012. Tr. 964; Resp’ts Ex. 89. When comparing the two maps, Mr. Greenberg noted that the top 100 prescribers for the March 2010 to February 2012 time period were not the same top 100 prescribers for the time period from January 2011 to February 2012. Tr. 967–68. Mr. Greenberg also created equivalent maps for Respondent 219 for the March 2010 to February 2012 (Respondents’ Exhibit 86) and for the January 2011 to February 2012 timeframe (Respondents’ Exhibit 87). Tr. 969–73. The maps indicate that a large number of out-of-area prescribers for each pharmacy in the first time frame is apparently reduced to a somewhat smaller number of out-of-area prescribers for each pharmacy in the second time frame.

Mr. Greenberg also testified to an analysis he conducted regarding a specific address in Deland, Florida. Tr. 986–87. In his analysis, Mr. Greenberg found that fifteen “unique” individuals had filled prescriptions for

oxycodone 30 mg at one or both of the Respondent Pharmacies during the two year time period from March 2010 through February 2012. Tr. 987. All told, the fifteen individuals filled sixty-six prescriptions for oxycodone 30 mg at the Respondent pharmacies. Tr. 989. However, the address field contained “specific apartment numbers * * * that clearly identified it as an apartment building with different units.” Tr. 987. Internet research revealed that the address was “an apartment complex with about 160 or so individual residential units in that complex.” Tr. 989.

There is no question that Mr. Greenberg presented as a sincere witness essaying to candidly and thoroughly answer questions asked of him. That said, other than highlighting the Respondents’ dispensing of controlled substances written by prescribers who were located at some distance from both pharmacies in contracting numbers, he did not offer testimony that shed any appreciable level of light on any issue to be resolved in this recommended decision.

The Respondents also presented the testimony of Joseph Abbott, the Vice President of Pharmacy Operations for CVS.⁷³ Tr. 1229. Mr. Abbott testified that he holds an undergraduate degree in electric engineering from Duke University and recently completed his coursework for an M.B.A. from the Wharton School at the University of Pennsylvania. Tr. 1229. Though he has been employed by CVS since 2006, Mr. Abbott testified that he assumed his role as Vice President of Pharmacy Operations in March of 2012. Tr. 1230. Prior to becoming the Pharmacy Operations V.P., Mr. Abbott was Senior Director of Pharmacy Operations Services, a position he held since January of 2011. Tr. 1302.

According to Mr. Abbott, the Pharmacy Operations Group is staffed by “about 50 people” and “provide[s] support to [CVS] pharmacy teams and * * * field management teams as it relates to policies and procedures. This includes communications of the policies and procedures as well as a definition of tools and training to support those policies and procedures.” Tr. 1230. As the Vice President of Pharmacy Operations, Mr. Abbott’s “primary responsibilities are to oversee the team that defines the procedures, defines the supporting tools, and [provide support to] the pharmacy teams and the field management teams.” Tr. 1230.

Abbott presented some testimony relative to the organization of prescribing data within the CVS computer systems that produced the data supplied to the Government and so

widely used in its case-in-chief. Mr. Abbott explained that the “agency type” field is a designation employed by CVS “to classify how the prescription is paid for.” Tr. 1234. When “cash” appears in the “agency type” field, that denotes a “general definition [that] refers to the fact that * * * the full retail price of the prescription would be paid for by the patient or an agent of the patient at the time the prescription is picked up. It can be paid through any means of tender—cash, credit card, check, debit card.” Tr. 1234. The term “cash discount” means that the full payment owed was paid for by the patient, but that “the patient [was] eligible for some form of discount due to their affiliation with some entity.” Tr. 1234–35.

Mr. Abbott also testified regarding a computer system called RxConnect, which is “[t]he primary pharmacy system” used by CVS pharmacists for the dispensing of controlled substances and other drugs. Tr. 1236. The RxConnect system “supports clinical checks as well as billing of third party claims.” Tr. 1236. To assist in the filling of prescriptions, the system displays “patient information, prescriber information, drug information [and] third party information related to the third party coverage.”⁷⁴ The term “[p]atient information” includes “the name, the date of birth, the address, the phone number, allergies that the patient has reported, medical conditions the patient has reported [and] history of prescription fills.” Tr. 1237. While identifying information of a patient may be edited by the pharmacy teams, the history of prescription fills is a product of the system. Tr. 1237–39.

Mr. Abbott explained that the CVS practice has been that when a patient dropped off a prescription at a pharmacy, the pharmacy team would search the system—by last name, date of birth or phone number—to ascertain whether the customer is already in the system. “If the patient’s record is already there, they would select the patient and have the opportunity to edit any of the key information about the patient.” Tr. 1239. If the patient is not in the system, “the pharmacy team would choose to add a patient [and] would enter in name, date of birth [and] address based on the information provided on the prescription or by the patient themselves.” Tr. 1240.

The RxConnect system also includes drug information. Tr. 1242. The drug information includes the drug name, the generic name (if applicable), the strength, the dosage form and the manufacturer. Tr. 1242–43. The system is accompanied by an industry standard automated drug utilization review system, which “look[s] at the patient’s prescription profile and identifi[es] potential drug interactions and so forth.” Tr. 1243.

Abbott explained that the prescriber information in the RxConnect system currently is supplied by a vendor of prescriber information (data aggregator) called Health Market Science (HMS). Tr. 1241–42. Though Mr. Abbott could not remember the exact datum RxConnect displays for each prescriber, he testified that

⁷² Mr. Greenberg’s CV was received into evidence. Resp’t Ex. 2.

⁷³ Holiday CVS LLC, the owner of the Respondent Pharmacies, is a wholly owned subsidiary of CVS Pharmacy Inc., which is, in turn, a wholly owned subsidiary of CVS/Caremark. Tr. 1231–32. Mr. Abbott testified that although he was not sure of the precise corporate structure under which he is employed by CVS, to the best of his understanding, he believed that he was employed by CVS/Caremark. Tr. 1232. The fact that the Vice President of Pharmacy Operations at CVS (who is about to receive an M.B.A. from the Wharton School) lacks an understanding over which aspect of CVS actually employs him is puzzling to say the least, but does not impact on any issue to be decided in this recommended decision.

⁷⁴ “Third party” information refers to a patient’s insurance plan. Tr. 1237.

the prescriber profile includes the physician's DEA number and address.⁷⁵ Tr. 1266. Other information would be available on other, "more detailed screens." Tr. 1267.

According to Mr. Abbott, HMS "aggregate[s]"⁷⁶ prescriber data from various sources and then suppl[ies] it to companies in a variety of industries." Tr. 1241. HMS obtains its prescriber information data from an entity called NTIS. Tr. 1247. NTIS, in turn, is a service provided by the Government which supplies prescriber information, including DEA registration data, to non-governmental entities. Tr. 1247. It is further his understanding that once HMS receives data from NTIS, they load it into their system, and then update the records in CVS's system. Tr. 1247. Abbott testified that HMS receives data from NTIS approximately once per week, and updates CVS's data once per week. Tr. 1247-48. HMS became the sole source of the prescriber information in April of 2012 (i.e., the month prior to the hearing in this matter). Tr. 1245.

Mr. Abbott testified that whenever a pharmacy team member attempts to fill a prescription, they must associate a prescriber to the prescription. Tr. 1248. In this regard, they must search for,⁷⁷ and select, the appropriate prescribing physician. Tr. 1248-49. Once the prescribing physician has been selected, the system checks the prescription against the physician's prescribing status. Tr. 1249. If the physician does not have authority to prescribe the drug called for by the prescription, then the system will display an error message and prevent the filling of the prescription. Tr. 1249, 1270. A pharmacy employee cannot override the system to fill a prescription for a practitioner who appears unregistered in RxConnect. Tr. 1270.

Prior to April of 2012, prescriber information was provided by HMS, but was also managed by the pharmacy teams at individual stores. Tr. 1245-46. Thus, if a pharmacy technician queried the system for a particular prescriber, RxConnect "would display both the HMS records as well as some of the historical store entered records from the past." Tr. 1246.

Mr. Abbott also addressed an anomaly in the way that CVS produced the historical records which made up the CVS Dispensing Data utilized during these proceedings. Tr. 1254-55. According to Abbott, when the warehouse pulls the data from RxConnect, it will reflect its current status as of the time the report is run. Tr. 1254-55. Put differently, because patient and prescriber information is subject to change, the patient and/or prescriber information reflected on the spreadsheets generated from the CVS Dispensing Data and introduced by the Government could well have been different from the information which appeared to the

Respondents' pharmacy staff at the time the controlled substances were actually dispensed. Tr. 1255-56. With this in mind, Mr. Abbott checked CVS's records and ascertained that the "do not fill" notations in the address field for Government Exhibit 35 were not associated with the Dr. Jumanni profile at the time the corresponding prescriptions were dispensed. Tr. 1256-59; 1262-63. Mr. Abbott indicated that he was able to divine this reached this conclusion by checking the "back tag sticker"⁷⁸ associated with the relevant prescriptions. Tr. 1262-63.

Mr. Abbott was also asked about the training that CVS provides to its "pharmacy team," which "includes the pharmacist * * * the pharmacy technicians [and the] pharmacy supervisors." Tr. 1263-64. The pharmacy team members receive new-hiring training, as well as "twice-a-year compliance and regulatory training, which includes controlled substance defense in training." Tr. 1264. The bi-annual compliance and regulatory training is made available to employees via an online management system. Tr. 1264. CVS is "able to track completion of [the biannual] training," and will identify individual employees who have not completed the required outlines. Tr. 1279-80. Dispensing guidelines with regard to controlled substances are sent the pharmacy teams through a program called Workload Manager, and are sent to the field management teams via email. Tr. 1274-75.

Abbott explained that in March and October of 2011, CVS disseminated its bi-annual training outlines ("October 2011 Guidelines").⁷⁹ Tr. 1275-76. Further, in late June of 2011, in response to the Florida Pill Legislation of July 1, 2011, CVS Corporate issued guidelines "for handling fraudulent or altered prescriptions" ("June 2011 Guidelines").⁸⁰ Tr. 1275; Resp'ts Ex. 27. Additionally, according to Mr. Abbott, in January of 2012, CVS "issued an enhanced set of guidelines for dispensing controlled substances" ("January 2012 Guidelines"). Tr. 1275; Resp'ts Ex. 34. The January 2012 Guidelines replaced a set of guidelines which had been submitted to the field pharmacies in December of 2010 ("December 2010 Guidelines").⁸¹ Tr. 1284; Resp'ts Ex. 23.

The December 2010 Guidelines, which were sent to CVS pharmacies on December 10, 2010, direct CVS PICs "to ensure [that] all Pharmacists and support staff understand[] their responsibilities as [they] relate[] to these Dispensing Guidelines."

⁷⁸ "Since that sticker prints out at the time of filling, all of the information on that sticker reflects what was on the patient record." Tr. 1263.

⁷⁹ Though the March 2011 outline was not introduced into evidence, excerpts from the October 2011 Outline were. Resp'ts Ex. 32.

⁸⁰ The June 2011 Guidelines were not associated with training. Tr. 1301. Rather, they "[were] an updated set of policies that [were] communicated to the stores and the field management teams." Tr. 1301. CVS sought to ensure understanding of the revised guidelines by organizing a conference call led by pharmacists at CVS. Tr. 1301.

⁸¹ Mr. Abbott explained that it was his "understanding" that the January 2012 Guidelines were produced in response to "feedback and guidance" CVS had received from DEA in the wake of the execution of the AIWs on the Respondent pharmacies. Tr. 1285.

Resp'ts Ex. 23. The December 2010 Guidelines state that:

(1) When considering the legitimacy of a prescription, a pharmacy team member should obtain a photo identification and record the patient's name, address and date of birth on the back of the prescription. Resp'ts Ex. 23, at 1-2.

(2) The team member should "[c]ontact the prescriber with any concerns about the type, dosage, frequent or amount of medication prescribed [and] document communications with [the] prescriber or agent on the back of the prescription to include date, time, outcome and name of person." Resp'ts Ex. 23, at 2.

(3) The pharmacy team members should "[e]xercise heightened scrutiny for prescriptions written by out-of-area doctors or presented by out-of-area patients for certain controlled substances (e.g., oxycodone or hydrocodone) especially new patients from the same prescriber." *Id.* The document directs the team member to "[v]erify out-of-area prescriptions with the prescriber and notify your Pharmacy Supervisor." *Id.*

Also, of relevance to these proceedings, the December 2010 Guidelines identify the following "warning signs [which] can assist in identifying inappropriate prescription-seeking behavior:" (1) "[p]atient insists on paying cash for a controlled substance prescription;" (2) "[p]atient insists on getting brand name controlled substances only;" and (3) "[p]rescribers consistently prescribe the same combination of drugs for most or all patients." *Id.*

The June 2011 Guidelines, define the pharmacist's corresponding responsibility, and provide that "[i]f a pharmacist believes a prescription is suspect, the pharmacist should investigate and/or verify the prescription to ensure the legitimacy of the order and to establish the identity of the prescriber and patient." Resp'ts Ex. 27. Beyond stating that pharmacists should exercise "heightened scrutiny" for "out-of-area" ⁸² oxycodone prescriptions, the June 2011 Guidelines provided four non-exhaustive steps for verifying prescriptions: (1) verifying the identity of the patient by obtaining a photo id; (2) reviewing the patient's profile for prior medication history; (3) contacting the prescriber; and (4) checking the state PMP. *Id.* The document further provides that "[a]ll communications with the prescriber's office should be documented on the back of the prescription, including the time, date, outcome and name of person with whom the pharmacist spoke at the prescriber's office." *Id.*

The October 2011 Guidelines and January 2012 Guidelines include minor changes to CVS's dispensing procedures which, for the reasons discussed below, played no part in these proceedings.

With regard to the issues underlying these proceedings, Mr. Abbott testified that "the company saw [the execution of the AIWs] as a significant event, and based on the

⁸² The phrase "out-of-area" appears throughout the Respondents' training documents. Mr. Abbott explained that the application of this term is store specific. Tr. 1300.

⁷⁵ A doctor may have multiple addresses. Tr. 1267-698.

⁷⁶ Mr. Abbott testified that it is important to have one source of aggregated data because "[i]t allows us to have one record for each prescriber and prevents to the greatest degree possible having incorrect information tied together." Tr. 1242.

⁷⁷ The search may be conducted through some combination of the prescriber's: (1) last name; (2) NPI number; (3) DEA number; or (4) phone number. Tr. 1248.

feedback, we thought it was prudent to take a number of actions in response.” Tr. 1285. In particular, Mr. Abbott testified that in the wake of the AIWs, CVS:

(1) Mandated 100-percent completion of bi-annual training. Tr. 1280.

(2) Created and distributed the January 2012 Guidelines. Tr. 1284.

(3) Ceased dispensing Schedule II controlled substances for prescriptions written by twenty-two⁸³ Florida prescribers. Tr. 1286. In this regard, the list of banned prescribers was posted in all 700 CVS pharmacies in the State of Florida. Tr. 1288.

(4) Developed a “comprehensive * * * training around dispensing of controlled substances as well as DEA record keeping” to serve as a “supplement to the bi-annual training.” Tr. 1286.

(5) Provided access to the Florida PDMP Web site, eForce, a prescription drug monitoring program. Tr. 1291–92.

(6) Began to develop a system for placing ordering limits for Florida pharmacies. Tr. 1291. Conducted a live training with field managers in the State of Florida regarding controlled substance dispensing. Tr. 1295; Resp’ts Ex. 35.

(7) Replaced the PICs at the Respondent pharmacies. Tr. 1294.

The rationale provided by Mr. Abbott as to why the Respondents replaced their PICs is particularly significant. Abbott explained the decision in this way:

[B]ased on the additional scrutiny within the stores related to these hearings, the company felt it was in the best interest of those pharmacies to bring in new leadership that would not be distracted by these events. Tr. 1294 (emphasis supplied). He went on to explain that CVS took these actions because “it takes its responsibility seriously, and given the * * * elevated level of drug abuse * * * that’s * * * in Florida, we don’t want to contribute to that, and to the extent that any of our stores could contribute to that, we wanted to take * * * steps to help ensure that no stores do [so] in the future.” Tr. 1296–97.

The testimony presented by Mr. Abbott was sufficiently detailed, consistent, and plausible to be fully credited in this recommended decision.

Additional facts required for a disposition of this matter are set forth in the Analysis.

The Analysis

Pursuant to 21 U.S.C. 824(a)(4) (2006), the Administrator⁸⁴ is permitted to revoke a COR if persuaded that the registrant “has committed such acts as would render * * * registration under section 823 * * * inconsistent with the public interest * * *.” The following factors have been provided by Congress in determining “the public interest”:

(1) The recommendation of the appropriate State licensing board or professional disciplinary authority.

(2) The [registrant’s] experience in dispensing, or conducting research with respect to controlled substances.

(3) The [registrant’s] conviction record under Federal or State laws relating to the manufacture, distribution, or dispensing of controlled substances.

(4) Compliance with applicable State, Federal or local laws relating to controlled substances.

(5) Such other conduct which may threaten the public health and safety.

21 U.S.C. 823(f) (2006 & Supp. III 2010).

“[T]hese factors are considered in the disjunctive.” *Robert A. Leslie, M.D.*, 68 FR 15227, 15230 (2003). Any one or a combination of factors may be relied upon, and when exercising authority as an impartial adjudicator, the Administrator may properly give each factor whatever weight she deems appropriate in determining whether a registration should be rejected. *Morall v. DEA*, 412 F.3d 165, 173–74 (D.C. Cir. 2005); *JLB, Inc., d/b/a Boyd Drugs*, 53 FR 43945, 43947 (1988); *David E. Trawick, D.D.S.*, 53 FR 5326, 5327 (1988); see also *Joy’s Ideas*, 70 FR 33195, 33197 (2005); *David H. Gillis, M.D.*, 58 FR 37507, 37508 (1993); *Henry J. Schwarz, Jr., M.D.*, 54 FR 16422, 16424 (1989). Moreover, the Administrator is “not required to make findings as to all of the factors * * *.” *Hoxie v. DEA*, 419 F.3d 477, 482 (6th Cir. 2005); see also *Morall*, 412 F.3d at 173–74. The Administrator is not required to discuss consideration of each factor in equal detail, or even every factor in any given level of detail. *Trawick v. DEA*, 861 F.2d 72, 76 (4th Cir. 1988) (the Administrator’s obligation to explain the decision rationale may be satisfied even if only minimal consideration is given to the relevant factors and remand is required only when it is unclear whether the relevant factors were considered at all). The balancing of the public interest factors “is not a contest in which score is kept; the Agency is not required to mechanically count up the factors and determine how many favor the Government and how many favor the registrant. Rather, it is an inquiry which focuses on protecting the public interest * * *.” *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 462 (2009).

In an action to revoke a registrant’s COR, the DEA has the burden of proving that the requirements for revocation are satisfied. 21 CFR 1301.44(e) (2011). The Government may sustain its burden by showing that the Respondent has committed acts inconsistent with the public interest. *Jeri Hassman, M.D.*, 75 FR 8194, 8235–36 (2010). Once DEA has made its *prima facie* case for revocation of the registrant’s COR, the burden of production then shifts to the respondent to present sufficient mitigating evidence to assure the Administrator that he or she can be entrusted with the responsibility commensurate with such a registration. *Steven M. Abbadessa, D.O.*, 74 FR 10077, 10078, 10081 (2009); *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008); *Samuel S. Jackson, D.D.S.*, 72 FR 23848, 23853 (2007); *Morall*, 412 F.3d at 174; *Humphreys*

v. DEA, 96 F.3d 658, 661 (3d Cir. 1996); *Shatz v. U.S. Dept. of Justice*, 873 F.2d 1089, 1091 (8th Cir. 1989); *Thomas E. Johnston*, 45 FR 72311, 72312 (1980). “[T]o rebut the Government’s *prima facie* case, [the respondent] is required not only to accept responsibility for [the established] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.” *Jeri Hassman, M.D.*, 75 FR at 8236. Normal hardships to the practitioner and even to the surrounding community that are attendant upon the lack of registration are not relevant considerations. *Linda Sue Cheek, M.D.*, 76 FR 66972, 66973 (2011); *Abbadessa*, 74 FR at 10078; see also *Gregory D. Owens, D.D.S.*, 74 FR 36751, 36757 (2009).

The Agency’s conclusion that past performance is the best predictor of future performance has been sustained on review in the courts, *Alra Labs. v. DEA*, 54 F.3d 450, 452 (7th Cir. 1995), as has the Agency’s consistent policy of strongly weighing whether a registrant who has committed acts inconsistent with the public interest has accepted responsibility and demonstrated that he or she will not engage in future misconduct. *Hoxie*, 419 F.3d at 483; *Ronald Lynch, M.D.*, 75 FR 78745, 78749 (2010) (Respondent’s attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.*, 75 FR 66138, 66140, 66145, 66148 (2010); *East Main Street Pharmacy*, 75 FR 66149, 66165 (2010); *George C. Aycock, M.D.*, 74 FR 17529, 17543 (2009); *Abbadessa*, 74 FR at 10078; *Krishna-Iyer*, 74 FR at 463; *Medicine Shoppe*, 73 FR at 387.

While the burden of proof at this administrative level is a preponderance-of-the-evidence standard, see *Steadman v. SEC*, 450 U.S. 91, 100–01 (1981), the Administrator’s factual findings will be sustained on review so long as they are supported by “substantial evidence.” *Hoxie*, 419 F.3d at 481. Thus, “the possibility of drawing two inconsistent conclusions from the evidence” does not limit the Administrator’s ability to find facts on either side of the contested issues in the case. *Shatz*, 873 F.2d at 1092; *Trawick*, 861 F.2d at 77. However, in rendering a decision, the Administrator must consider all “important aspect[s] of the problem,” such as a Respondent’s defense or explanation that runs counter to the Government’s evidence. *Wedgewood Vill. Pharmacy v. DEA*, 509 F.3d 541, 549 (D.C. Cir. 2007); *Humphreys*, 96 F.3d at 663. The ultimate disposition of the case must be in accordance with the weight of the evidence, not simply supported by enough evidence to justify, if the trial were to a jury, a refusal to direct a verdict when the conclusion sought to be drawn from it is one of fact for the jury. *Steadman*, 450 U.S. at 99 (internal quotation marks omitted).

Regarding the exercise of discretionary authority, the courts have recognized that gross deviations from past agency precedent must be adequately supported. *Morall*, 412 F.3d at 183. Mere unevenness in application standing alone does not, however, render a particular discretionary action unwarranted. *Chein v. DEA*, 533 F.3d 828, 835 (D.C. Cir. 2008) (citing *Butz v. Glover Livestock Comm.*

⁸³Mr. Abbott did not know why any of the doctors had been banned. Tr. 1298. Mr. Abbott further testified that he believed at least one of these prescribers was removed from the do not fill list. Tr. 1304–05.

⁸⁴This authority has been delegated pursuant to 28 CFR 0.100(b) and 0.104 (2010).

Co., 411 U.S. 182, 188 (1973)), *cert. denied*, ___ U.S. ___, 129 S. Ct. 1033, 1033 (2009). It is well-settled that since the Administrative Law Judge has had the opportunity to observe the demeanor and conduct of hearing witnesses, the factual findings set forth in a recommended decision are entitled to significant deference. *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 496 (1951). Thus, a recommended decision constitutes an important part of the record that must be considered in the Administrator's decision. *Morall*, 412 F.3d at 179. However, any recommendations set forth herein regarding the exercise of discretion are not binding on the Administrator and do not limit the exercise of that discretion. 5 U.S.C. 557(b) (2006); *River Forest Pharmacy, Inc. v. DEA*, 501 F.2d 1202, 1206 (7th Cir. 1974); *Attorney General's Manual on the Administrative Procedure Act* 8 (1947).

Factors 1 and 3: The Recommendation of the Appropriate State Licensing Board or Professional Disciplinary Authority, and Conviction Record Under Federal or State Laws Relating to the Manufacture, Distribution, or Dispensing of Controlled Substances

Regarding Factor 1, the record contains no evidence of a recommendation regarding the Respondents' privileges to operate as a pharmacy by any cognizant state licensing board or professional disciplinary authority. However, the fact that a state has not acted against a registrant's license is not dispositive in this administrative determination as to whether continuation of a registration is consistent with the public interest. *Patrick W. Stodola, M.D.*, 74 FR 20727, 20730 (2009); *Jayam Krishna-Iyer*, 74 FR at 461. It is well-established Agency precedent that a "state license is a necessary, but not a sufficient condition for registration." *Leslie*, 68 FR at 15230; *John H. Kennedy, M.D.*, 71 FR 35705, 35708 (2006). Even the reinstatement of a state license does not affect the DEA's independent responsibility to determine whether a registration is in the public interest. *Mortimer B. Levin, D.O.*, 55 FR 9209, 8210 (1990). The ultimate responsibility to determine whether a registration is consistent with the public interest has been delegated exclusively to the DEA, not to entities within state government. *Edmund Chein, M.D.*, 72 FR 6580, 6590 (2007), *aff'd*, *Chein v. DEA*, 533 F.3d 828 (D.C. Cir. 2008), *cert. denied*, ___ U.S. ___, 129 S.Ct. 1033 (2009). Congress vested authority to enforce the CSA in the Attorney General and not state officials. *Stodola*, 74 FR at 20375. Thus, on these facts, the fact that the record contains no evidence of a recommendation by a state licensing board does not weigh for or against a determination as to whether the Respondents' continued registrations with DEA would be consistent with the public interest.

Regarding the third factor (convictions relating to the manufacture, distribution, or dispensing of controlled substances), the record in this case does not contain evidence that the Respondents have been convicted of (or charged with) a crime related to the manufacture, distribution, or dispensing of controlled substances. DEA administrative

proceedings are non-punitive and "a remedial measure, based upon the public interest and the necessity to protect the public from those individuals who have misused controlled substances or their DEA COR, and who have not presented sufficient mitigating evidence to assure the [Administrator] that they can be trusted with the responsibility carried by such a registration." *Jackson*, 72 FR at 23853; *Leo R. Miller, M.D.*, 53 FR 21931, 21932 (1988). Where evidence in a particular case reflects that the Respondent has acquired convictions relating to the manufacture, distribution, or dispensing of controlled substances, those convictions must be carefully examined and weighed in the adjudication of whether the issuance of a registration is in the public interest. 21 U.S.C. 823(f).

Although the standard of proof in a criminal case is more stringent than the standard required at an administrative proceeding, and the elements of both federal and state crimes relating to controlled substances are not always co-extensive with conduct that is relevant to a determination of whether registration is within the public interest, evidence that a registrant has been convicted of crimes related to controlled substances is a factor to be evaluated in reaching a determination as to whether he or she should be entrusted with a DEA certificate. The probative value of an absence of any evidence of criminal prosecution is somewhat diminished by the myriad of considerations that are factored into a decision to initiate, pursue, and dispose of criminal proceedings by federal, state, and local prosecution authorities. *See Robert L. Dougherty, M.D.*, 76 FR 16823, 16833 n.13 (2011); *Dewey C. Mackay, M.D.*, 75 FR 49956, 49973 (2010) ("[W]hile a history of criminal convictions for offenses involving the distribution or dispensing of controlled substances is a highly relevant consideration, there are any number of reasons why a registrant may not have been convicted of such an offense, and thus, the absence of such a conviction is of considerably less consequence in the public interest inquiry"), *aff'd*, *Mackay v. DEA*, 664 F.3d 808 (10th Cir. 2011); *Ladapo O. Shyngle, M.D.*, 74 FR 6056, 6057 n.2 (2009).

Accordingly, consideration of the evidence of record under the first and third factors neither supports the Government's argument for revocation nor militates against it.

Factors 2 and 4: The Respondent's Experience in Dispensing Controlled Substances, and Compliance With Applicable State, Federal or Local Laws Relating to Controlled Substances

Agency precedent has consistently held that the registration of a pharmacy may be revoked as the result of the unlawful activity of the pharmacy's owners, majority shareholders, officers, managing pharmacist or other key employee. *EZRX, LLC*, 69 FR 63178, 63181 (1988); *Plaza Pharmacy*, 53 FR 36910 (1988). The gravamen of the Government's allegations and evidence in this case focuses on the manner in which the Respondent, through its agents, dispensed controlled substances. Factors two and four are most relevant to this analysis.

Regarding Factor Two, in requiring an examination of a registrant's experience in dispensing controlled substances, Congress manifested an acknowledgement that the qualitative manner and the quantitative volume in which a registrant has engaged in the dispensing of controlled substances may be significant factors to be evaluated in reaching a determination as to whether a registrant should be (or continue to be) entrusted with a DEA COR. In some (but not all) cases, viewing a registrant's actions against a backdrop of how she has performed activity within the scope of the certificate can provide a contextual lens to assist in a fair adjudication of whether continued registration is in the public interest. In this regard, however, the Agency has applied principles of reason, coupled with its own expertise in the application of this factor. For example, the Agency has taken the reasonable position that this factor can be outweighed by acts held to be inconsistent with the public interest. *Jayam Krishna-Iyer*, 74 FR at 463; *see also Jeri Hassman, M.D.*, 75 FR 8194, 8235 (2010) (acknowledging Agency precedential rejection of the concept that conduct which is inconsistent with the public interest is rendered less so by comparing it with a respondent's legitimate activities which occurred in substantially higher numbers); *Paul J. Cargine, Jr.*, 63 FR 51592, 51560 (1998) ("[E]ven though the patients at issue are only a small portion of Respondent's patient population, his prescribing of controlled substances to these individuals raises serious concerns regarding [his] ability to responsibly handle controlled substances in the future."). Similarly, in *Cynthia M. Cadet, M.D.*, 76 FR 19450, 19450 n.1 (2011), the Agency determined that existing List I precedent⁸⁵ holding that experience related to conduct within the scope of the COR sheds light on a practitioner's knowledge of applicable rules and regulations, would not be applied to cases where intentional diversion allegations were sustained. The Agency's approach in this regard has been sustained by on review. *Mackay*, 664 F.3d at 819.

Regarding Factor Four (compliance with laws related to controlled substances), to effectuate the dual goals of conquering drug abuse and controlling both legitimate and illegitimate traffic in controlled substances, "Congress devised a closed regulatory system making it unlawful to manufacture, distribute, dispense, or possess any controlled substance except in a manner authorized by the CSA." *Gonzales v. Raich*, 545 U.S. 1, 13 (2005). Under the regulations, "[t]he responsibility for the proper prescribing and dispensing of controlled substances is upon the prescribing practitioner, but a corresponding responsibility rests with the pharmacist who fills the prescription." 21 CFR 1306.04(a). Under this language, a pharmacist has a duty "to fill only those prescriptions that conform in all respects with the requirements of the [CSA] and DEA regulations, including the requirement that the prescribing practitioner be properly registered." *Electronic*

⁸⁵ *See, e.g., Volusia Wholesale*, 69 FR 69409, 69410 (2004).

Prescriptions for Controlled Substances, 75 FR 16236, 16266 (2010). In short, a pharmacist has a “corresponding responsibility under Federal law to dispense only lawful prescriptions.” *Liddy’s Pharmacy, L.L.C.*, 76 FR 48887, 48895 (2011). The corresponding responsibility to ensure the dispensing of valid prescriptions extends to the pharmacy itself. *Medicine Shoppe-Jonesborough*, 73 FR 364, 384 (2008) (Finding that a respondent pharmacy was properly charged with violating corresponding responsibility); *See also United Prescription Services, Inc.*, 72 FR 50397, 50407–08 (2007) (same). *See Drug Enforcement Administration, Issuance of Multiple Prescriptions for Schedule II Controlled Substances*, 72 FR 64921, 69424 (2007) (referring to a pharmacy’s corresponding responsibility); *see also Drug Enforcement Administration, Role of Authorized Agents in Communicating Controlled Substance Prescriptions to Pharmacies*, 75 FR 61613, 61617 (2010) (Referring to a pharmacies “corresponding responsibility regarding the dispensing of controlled substances.”); *EZRX, LLC*, 69 FR at 63181 (“DEA has issued orders to show cause and subsequently revoked the DEA registrations of pharmacies which failed to fulfill their corresponding responsibility in Internet prescribing operations.”) (emphasis added). Settled Agency precedent has interpreted this corresponding responsibility as prohibiting the filling of a prescription where the pharmacist or pharmacy “knows or has reason to know” that the prescription is invalid.⁸⁶ *Bob’s Pharmacy & Diabetic Supplies*, 74 FR 19599, 19601 (2009) (citing *Medicine Shoppe-Jonesborough*, 73 FR at 381 (quoting *Medic-Aid Pharmacy*, 55 FR 30043, 30044 (1990))); *See also United Prescription Services, Inc.*, 72 FR 50397, 50407–08 (2007) (Finding violation of corresponding responsibility where pharmacy “had ample reason to know” that the practitioner was not acting in the usual course of professional practice).

DEA has interpreted the “legitimate medical purpose” feature of the corresponding responsibility duty “as prohibiting a pharmacist from filling a prescription for a controlled substance when he either knows or has reason to know that the prescription was not written for a legitimate medical purpose,” and has been equally consistent in its admonishment that “[w]hen prescriptions are clearly not issued for legitimate medical purposes, a pharmacist may not intentionally close his eyes and thereby avoid [actual] knowledge of the real

purpose of the prescription.” *Sun & Lake Pharmacy, Inc.*, 76 FR 24523, 24530 (2011); *Liddy’s Pharmacy, L.L.C.*, 76 FR at 48895; *East Main Street Pharmacy*, 75 FR 66149, 66163 (2010); *Lincoln Pharmacy*, 75 FR 65667, 65668 (2010); *Bob’s Pharmacy*, 74 FR at 19601. The Agency does not require omniscience. *Carlos Gonzalez*, 76 FR 63118, 63142 (2011) (citing *Holloway Distrib.*, 72 FR 42118, 42124 (2007)). However, when the circumstances surrounding the presentation of a prescription would give rise to suspicion in a “reasonable professional,” there is a duty to “question the prescription[.]” *Bertolino*, 55 FR at 4730. Though initially framed as a “reasonable professional” standard, the Agency has considered the duty to discharge the corresponding responsibility by evaluating the circumstances in light of what would be considered suspicious by a “reasonable pharmacist.” *East Main Street Pharmacy*, 75 FR at 66165; *see also Winn’s Pharmacy*, 56 FR 52559, 52561 (1991). Accordingly, a pharmacist or pharmacy may not dispense a prescription in the face of a red flag (i.e., a circumstance that does or should raise a reasonable suspicion as to the validity of a prescription) unless he or it takes steps to resolve the red flag and ensure that the prescription is valid. *Id.* Because Agency precedent limits the corresponding responsibility to circumstances which are known or should have been known, *Sun & Lake Pharmacy, Inc.*, 76 FR at 24530, it follows that, to show a violation of a corresponding responsibility, the Government must establish that: (1) the Respondent dispensed a controlled substance; (2) a red flag was or should have been recognized at or before the time the controlled substance was dispensed; and (3) the question created by the red flag was not resolved conclusively prior to the dispensing of the controlled substance. *See Sun & Lake Pharmacy*, 76 FR at 24532 (Finding that pharmacy violated corresponding responsibility where it took no steps to resolve red flags prior to dispensing controlled substances.). The steps necessary to resolve the red flag conclusively will *perforce* be influenced by the nature of the circumstances giving rise to the red flag.

When considering whether a pharmacy has violated its corresponding responsibility, the Agency considers whether the *entity*, not the pharmacist, can be charged with the requisite knowledge. *See United Prescription Services*, 72 FR 50397, 50407 (Respondent pharmacy violated corresponding responsibility because “an entity which voluntarily engages in commerce [to] other States is properly charged with knowledge of the laws regarding the practice of medicine in those States.”). *See also Pharmboy Ventures Unlimited, Inc.*, 77 FR 33770, 33772 n.2 (2012) (“DEA has long held that it can look behind a pharmacy’s ownership structure to determine who makes decisions concerning the controlled substance business of a pharmacy.”); *S&S Pharmacy, Inc.*, 46 FR 13051, 13052 (1981) (the corporate pharmacy acts through the agency of its PIC). Knowledge obtained by the pharmacists and other employees acting within the scope of their employment may be imputed to the pharmacy itself. *See U.S. v. One Parcel of*

Land, 965 F.2d 311, 316 (7th Cir.1992) (“Only knowledge obtained by corporate employees acting with the scope of their employment is imputed to the corporation.”).

In support of its allegation that the Respondents have violated their corresponding responsibilities, the Government has introduced evidence that the Respondent pharmacies: (1) dispensed controlled substances issued by prescribing physicians who lacked authority to prescribe the controlled substances that were dispensed (Lack of Valid Prescriber Authority); and (2) dispensed controlled substances under circumstances that would lead a reasonable pharmacist to have sufficient doubt about whether the prescriptions were issued for legitimate medical purposes by practitioners acting in the usual course of a professional practice (Questionable Circumstances).

Lack of Valid Prescriber Authority.

The uncontroverted evidence of record establishes that both Respondent pharmacies dispensed controlled substances on prescriptions issued by Dr. Wicks when he no longer possessed authority to issue such prescriptions. The Government’s evidence demonstrates thirty-eight (38) dispensing events where Respondent 219 dispensed controlled substances for Wicks prescriptions after his DEA COR expired on May 31, 2011. Tr. 468; Gov’t Ex. 26. Respondent 5195 dispensed controlled substances seventeen (17) times after Wicks’ COR expired. Tr. 469. Respondent 5195 filled Dr. Wicks’ oxycodone prescriptions as late as July 14, 2011, and Respondent dispensed on Wicks’ oxycodone prescriptions as late as July 15, 2011. Gov’t Ex. 10 at 6.

Likewise uncontroverted record evidence establishes that the DEA revoked the COR of Dr. Lynch, effective January 18, 2011, thereby depriving him of the authority to prescribe, administer or dispense any controlled substances. Tr. 66; *see also*, Gov’t Ex. 32 at 3–12. On that date, the DEA Web site maintained for registrants would have reflected that Lynch’s registration was “expired.” Tr. 74–75. It is beyond argument that Respondent 219 dispensed controlled substances pursuant to prescriptions written by Dr. Lynch no fewer than twenty-seven (27) times after his COR was revoked by the Agency. Gov’t Ex. 32. Of these twenty-seven prescriptions, seven were dispensed later than June of 2011. Gov’t Ex. 32, at 5, 7. Respondent 5195 filled four prescriptions after the January 18, 2011, revocation, one of which occurred in June. Gov’t Ex. 32, at 12. Thus, the Respondent pharmacies were dispensing controlled substances on Dr. Lynch’s prescriptions approximately five months (and more) after he had lost his authority to prescribe them.

It would be difficult to imagine a duty of a pharmacy registrant that is more fundamental to the law and spirit of the CSA than the obligation to ensure that controlled substance prescriptions are issued only on the authority of those empowered to prescribe by the DEA. *See Liddy’s Pharmacy*, 76 FR at 48895 (defining “corresponding responsibility under Federal law to dispense only lawful prescriptions.”). Absent

⁸⁶In addition to the foregoing, under Florida law a pharmacist will be subject to discipline if he or she “dispens[es] any medicinal drug based upon a communication that purports to be a prescription * * *. When the pharmacist knows or has reason to believe that the purported prescription¹ is not based upon a valid practitioner-patient relationship.” Fla. Stat. § 465.016(1)(s). In *Trinity Health Care Corp.*, 72 FR at 30854, the Agency acknowledged that the Florida state standard reflects essentially the same standard present in the DEA regulations which makes it unlawful to for a pharmacy registrant to intentionally look the other way “to avoid [actual] knowledge of the real purpose of [an illegitimate] prescription.” *Bertolino*, 55 FR at 4730.

confirmation of a COR, a prescription written by one without COR authority would authorize the routine distribution of dangerous narcotics on the approval anyone from the uninformed to the malevolent. In this vein, the *DEA Pharmacists Manual* (a copy of which was introduced into the record at the Respondent's request) specifically provides that controlled substance prescriptions may only be issued by a practitioner who is, *inter alia*, "[r]egistered with DEA or exempted from registration." *DEA Pharm. Man.* § IX. The terms of this requirement are replicated in 21 CFR 1306.03(a), which provides that, "[a] prescription for a controlled substance may be issued only by an individual practitioner who is: (1) Authorized to prescribe controlled substances by the jurisdiction in which he is licensed to practice his profession and (2) Either *registered* or exempted from registration pursuant to §§ 1301.22(c) and 1301.23 of this chapter." (emphasis added).

Because a prescription issued pursuant to an expired (or revoked) COR is invalid, 21 CFR 1306.03, it follows that the expiration of a COR is a clear red flag that a prescription issued pursuant to that COR is invalid. *Liddy's Pharmacy*, 76 FR at 48895; *Electronic Prescriptions for Controlled Substances*, 75 FR at 16266. Accordingly, the prescriptions issued pursuant to the invalid CORs of Drs. Wicks and Lynch, presented red flags. Having reached this conclusion, the question becomes whether the expirations of the CORs were recognized, or should have been recognized, by the Respondents.

The Respondents argue that they should be shielded from accountability in this regard because the commercial software they employed had a lag time. Even if the accuracy of this position were conceded, *arguendo*, it would afford them no quarter here.⁸⁷ The undisputed testimony in this matter establishes that CVS employs a third-party vendor (HMS) for its registration verification and that HMS receives its data directly from NTIS, a government Web site. Tr. 1247. HMS receives weekly updates from NTIS, and CVS receives weekly updates from HMS. Tr. 1247–48. Thus, notice of a registration action would reach CVS no later than two weeks from the date of the action. *Id.* Dr. Wicks's registration expired on May 31, 2011, while Dr. Lynch's registration was revoked on January 18, 2011. Accordingly, even under their own theory, the Respondents are accountable with notice of Dr. Wicks's expiration on June 15, 2011,⁸⁸ and notice of Dr. Lynch's revocation on February 2, 2011. In this regard, Respondent 5195

dispensed controlled substances pursuant to post-expiration Wicks prescriptions twelve times on or after June 15, 2011. Gov't Ex. 27. Respondent 219 dispensed controlled substances under similar circumstances twenty-seven times. Gov't Ex. 28. Similarly, all but one of the post-revocation Dr. Lynch dispensings occurred after February 2, 2011. Simply put, the Respondent pharmacies knew or should have known of the relevant registration statuses for the overwhelming majority of the post-expiration dispensings under either theory.

Turning to third prong of the inquiry—resolution—the record is clear that neither Dr. Wicks nor Dr. Lynch's⁸⁹ registration statuses could have been resolved conclusively to warrant dispensing of a controlled substance. DI Langston testified that, if a pharmacist is confronted with an invalid DEA number, the red flag may be resolved by a phone call to the DEA. Tr. 103. Because neither Dr. Wicks nor Dr. Lynch regained authority to prescribe after the dates of expiration/registration, a call to the DEA could not have resolved the red flag in favor of dispensing. Therefore, substantial evidence supports the conclusion that the red flags raised by the doctors' registration statuses were not resolved conclusively prior to dispensing.

Accordingly, it is clear that, on numerous occasions, the Respondents dispensed controlled substances in the face of recognizable and unresolvable red flags (expired registration numbers) that put them on notice that the controlled substance prescriptions were not issued in the usual course of a professional practice. 21 CFR 1306.04(a). Such acts are sufficient for the Government to sustain its burden in establishing its *prima facie* case for revocation.⁹⁰

Questionable Circumstances.

The record also contains evidence of many dispensing events that were attended by circumstances that raised red flags that required resolution. The Government's expert opined that, in many of these circumstances, the confluence of red flags were such that a

reasonable pharmacist could not have dispensed pursuant to the prescription while complying with the requirements of his or her corresponding responsibility. *See* Tr. 764–765. The Respondents contend that this testimony must be rejected because: (1) "Professor Doering's testimony is not based on a reliable methodology," Resp'ts Brief, at 92; (2) Professor Doering's opinion is based on bias, Resp'ts Brief, at 95; (3) Professor Doering did not look at the hard copies of any prescriptions when rendering his opinion, Resp'ts Brief, at 98; and (4) the evidence does not support Professor Doering's opinions, Resp'ts Brief, at 104. The first two contentions have been considered, and rejected, above. The third argument, which invokes Professor Doering's methodology, must be rejected for the same reasons as the second. Thus, the question becomes whether Professor Doering's opinion that certain combinations of red flags could not have been conclusively resolved was supported by substantial evidence.

As explained above, Professor Doering testified that, in some circumstances, resolution of red flags would be impossible "[b]ecause the methods that are available are flawed, and presenting identification simply identified the individual as the person presenting the prescription, and phoning the practitioner is so subject to fraud and deceit that even if a practitioner told me or his representative that, yes, the doctor wrote those that's not good enough for me." Tr. 764. The Respondents argue that this conclusion misstates the value of verification and contacting; and also that "the evidence clearly shows that Respondents did much more to evaluate and verify the legitimacy of prescriptions presented." Resp'ts Brief, at 104.

The Respondents have consistently and repeatedly urged that these two methods (verification and contacting) circumscribe the entire impossible duty upon a pharmacy registrant and defend this approach on multiple levels.⁹¹ The Respondent's expert, Professor Brushwood, distilled his understanding of pharmacy registrant obligations under his VIGIL protocol, which, as discussed at length, *supra*, essentially verifies only through "verification" (V), contacting the prescriber's office, and "identification" (I), seeking government-issued identification from the scrip presenter. Tr. 1021, 1030. The position of the Government's expert that these methods are of no avail when the scenario includes a complicit prescriber and/or a diverting presenter⁹² is logically more persuasive. In fact, the Respondents' expert ultimately conceded that checking ID and contacting a prescriber will not uniformly be sufficient to resolve every red flag. Tr. 1148. Thus, both experts who presented testimony at the hearing concurred that an ID check coupled with a prescriber contact (the only types of verification employed by the Respondent

⁸⁷ If the law were as the Respondents urge, then only those registrants who engage reliable and current software systems could be held accountable for dispensing controlled substances on the authorization of the unregistered or improperly registered. Suffice it to say that such a structure would hardly encourage responsible purchasing decisions by DEA registrants (or even consistent and cogent legal counsel by those advising them).

⁸⁸ In their post-hearing brief, the Respondents claim that the date of notice of the Wicks Expiration was two weeks after July 1, 2011, the date the registration was "retired." Resp'ts Brief, at 119 n. 116. This is contrary to the testimony. DI Langston testified that a number will appear as "expired" on the date of expiration. Tr. 79, 102–03.

⁸⁹ Admittedly, beyond the three scrips that were written on behalf of patient T.N. and dispensed by Respondent 219 (Gov't Ex. 33), the Government did not introduce evidence regarding the dates that Dr. Lynch's prescriptions were actually issued by him. However, the **Federal Register** entry ordering revocation, which was published prior to dispensing, indicates that the Agency found that Dr. Lynch had engaged in the unauthorized practice of medicine and had issued prescriptions which "lacked a legitimate medical purpose." Gov't Ex. 31 at 3–12; *Ronald Lynch M.D.*, 75 FR 78745, 78753 (2010). Thus, at the time the controlled substances were dispensed, not only did Dr. Lynch lack authority, but the public notice announced that his privileges were revoked for issuing illegitimate controlled substance prescriptions. Significantly, Paras Priyadarshi, the Respondent 219 PIC, indicated to GS Carter that he did not fill prescriptions written by certain doctors because "they had prior action taken against them." Tr. 252, 933.

⁹⁰ Having reached this conclusion, this opinion will not address whether the dispensing of prescriptions pursuant to Dr. Wicks's California registration could rise to the level of a violation of the corresponding responsibility.

⁹¹ Respondent 5195 PIC Merrill testified that some other measures were utilized "sometimes." Tr. 235–36.

⁹² Tr. 699.

pharmacies) will not always be sufficient to resolve red flags.

In further support of their assertion that verification and contact are valid means of resolution, the Respondents point to written guidance distributed by the DEA and the State of Florida. First, the Respondents cite to Florida Administrative Code § 64B16–27.823,⁹³ which, in pertinent part, directs pharmacists to contact the prescribing physician and verify identification when a combination of any two of five enumerated red flags is encountered.⁹⁴ The Respondents take the position that “[t]here are no other formal standards in Florida that govern pharmacists for purposes of dispensing controlled substances.” Resp’t Brief at 11.

Employing similar logic, the Respondents point to Appendix D of the *DEA Pharmacist’s Manual*,⁹⁵ which provides, *inter alia*, that [w]hen there is a question about any aspect of the prescription order, the pharmacist should contact the prescriber for verification or clarification [and] if at any time a pharmacist is in doubt, he/she should require proper identification.

Id. The Respondents urge that “[t]here is no other guidance from the DEA or any other federal entity with regard to the exercise of a pharmacist’s corresponding responsibility.” Resp’t Brief at 15.

Thus, the Respondents appear to argue that, because Florida and DEA have published sources that list prescriber contact and ID check procedures, that no other measures are required. The Respondents’ posture in this regard is illusory, inconsistent with the testimony of its expert witness, and even internally inconsistent with its own arguments. While positing that isolated lines from Appendix D of the *DEA Pharmacist’s Manual* and Florida Administrative Code § 64B16–27.823 comprise the entire universe of correct steps to resolve controlled substance prescribing red flags, the Respondents have simultaneously argued that

[t]he process of identifying and resolving red flags requires the exercise of individual professional judgment. Different pharmacists can have a different approach to dealing with red flags, and can reach different conclusion, but that does not mean they are not both exercising their corresponding responsibility. Resp’t Brief at 8 (internal record citations omitted). It would be difficult to reconcile the Respondents’ argument that prescriber contact and ID check are the sole means of red flag resolution with their simultaneous position that the process of identifying and resolving red flags should be entrusted to multiple valid approaches by individual pharmacists.

⁹³ A copy of which was received into evidence. Resp’t Ex. 20.

⁹⁴ The specified red flags are (a) frequent loss of controlled substance medications; (b) only controlled substance medications are prescribed for a patient; (c) one person presents controlled substance prescriptions with different patient names; (d) same or similar controlled substance medication is prescribed by two or more prescribers at same time; (e) patient always pays cash and always insists on brand name product. *Id.*

⁹⁵ A copy of which was received into evidence at the Respondents’ request. Resp’t Ex. 19.

The Respondents’ position that prescriber contact and ID check are the alpha and omega of red flag resolution also flies in the face of common sense. By adopting this argument the Agency would be endorsing an approach wherein a pharmacist who had even actual knowledge of intentional diversion on the part of prescriber and/or patient could completely discharge his duties to ensure a closed regulatory system by doing no more than ascertaining the true identity of the scrip presenter and procuring assurances from a complicit prescriber. While mindful of the established maxim that a specific provision controls over one of more general application,⁹⁶ the proposed interpretation of a pharmacist’s obligations based on the offered sources would present a ludicrous result that was obviously never intended by the drafters of the Florida Administrative Code or the *DEA Pharmacist’s Manual*, and are not endorsed in this recommended decision. *Chowdhury v. Ashcroft*, 241 F.3d 848, 853 (7th Cir. 2001) (“regulations * * * should not be so strictly interpreted as to provide unreasonable, unfair, and absurd results.”); *see also State v. Iacovone*, 660 So.2d 1371, 1373 (Fla. 1995) (“[s]tatutes as a rule will not be interpreted so as to yield an absurd result.”) (internal punctuation omitted) Professor Doering credibly and persuasively testified that the provisions in the Florida Administrative Code do not provide an exhaustive compilation of a pharmacist’s obligation, and that “[t]he standards of care * * * are not always determined by law, by statute, by rule [but are] determined, in fact, by what pharmacists do under like, or similar circumstances.” Tr. 921. On this point, the Respondent’s expert, Professor Brushwood, agreed. Tr. 1091. Professor Brushwood stated that the use of a pharmacist’s professional judgment goes beyond the factors set forth in the Florida Administrative Code. Tr. 1049–50. The pharmacy registrant’s duty that ripens while acting as a reasonable professional to question a controlled substance prescription, based on the circumstances surrounding the presentation of the scrip,⁹⁷ must be and is, much richer than the inexorable execution of a mechanical ID check and prescriber call. Merely effecting either or both of these steps will not, in all circumstances somehow magically absolve a DEA registrant of all responsibility stemming from dispensing a controlled substance pursuant to an illegitimate prescription. To be clear, verification and contact are useful for resolving specific types of red flags. *See* Tr. 764. However, the situational values of these two means of resolution do not undermine Professor Doering’s conclusion (concurrent in by Professor Brushwood) that their use will not discharge a corresponding responsibility in all circumstances.

Turning to the Respondents’ contention that their pharmacists performed checks beyond verification and contact—even assuming *arguendo* that the pharmacists performed all the checks alleged, the record stands uncontradicted that “the methods that

are available are flawed.” Tr. 764. Indeed, no expert who testified actually presented any manner in which the presented combination of red flags actually could be resolved. Thus, the fact that the Respondents may have employed additional procedures when attempting to establish the validity of the prescriptions does not undermine Professor Doering’s testimony that the particular combination of red flags were unresolvable and that the controlled substance prescriptions just should not have been dispensed. As discussed, *supra*, the credible and persuasive evidence of record establishes that in the credited opinion of the Government’s expert, on various occasions, each of the Respondents dispensed controlled substances in the face of red flags that were or should have been recognized, and that could not have been resolved to the satisfaction of a reasonably prudent pharmacist.

In its brief, the Government highlights many dispensing events that did not have the benefit of explanatory testimony from its expert witness. Given the number and strength of the instances that were the subject of Professor Doering’s testimony, it is not necessary to determine whether his expert opinions should be extrapolated to events over which he was not queried and cross-examined at the hearing.

As discussed, *supra*, Professor Doering described multiple dispensing events on multiple dates from both Respondents that evidenced red flags that could not, in his expert opinion, have been sufficiently resolved to warrant filling the prescriptions. The testimony from Professor Brushwood, that there may be information set forth in a patient profile database that could theoretically resolve these red flags is simply not persuasive on this record.⁹⁸ In any event, the only two forms of verification offered by Professor Brushwood in this VIGIL model and his review of Respondents’ operating procedures were presenter ID check and practitioner contact. Professor Doering convincingly testified that these two avenues would provide little insight in scenarios where patient and/or physician were complicit in diversion; a condition that

⁹⁶ In *Int’l Union (UAW) v. NLRB*, 459 F.2d 1329, 1336 (D.C. Cir. 1972), the United States Court of Appeals for the District of Columbia Circuit held that National Labor Relations Board committed reversible error by declining to apply the “adverse inference rule” where one of the parties had “relevant evidence within his control which he failed to produce.” The applicability of the adverse inference rule is not dependent upon the issuance of a subpoena seeking to compel production. *Int’l Union v. NLRB*, 459 F.2d at 1338. This precedent was embraced by the Eleventh Circuit in *Callahan v. Schultz*, 783 F.2d 1543, 1545 (11th Cir. 1986). The judicious utilization of the adverse inference rule allows an administrative tribunal to use the tools available to it and “permits vindication of the tribunal’s authority in situations where vindication might, as a practical matter, be impossible otherwise.” *Int’l Union v. NLRB*, 459 F.2d at 1339. While the present record provides more than ample basis for the application of an adverse inference that material in the Respondents’ patient profile databases would not be helpful to their cases, this case can be decided without the need to apply such an inference.

⁹⁷ *Cf. Gozion-Peretz v. United States*, 498 U.S. 395, 407 (1991).

⁹⁸ *Bertolino*, 55 FR at 4730.

Doering believed was likely based on the transactions he reviewed.

The statements and actions of the Respondents' employees speak volumes on the culture that existed in the two pharmacies whose conduct is the subject of these proceedings. The PICs and other employees from both Respondent pharmacies told DEA investigators that there was a practice that oxycodone prescriptions would be shut off at a given time each day.⁹⁹ Respondent 5195 PIC Jessica Merrill stated that she could fill oxycodone prescriptions all day, but that the pharmacist on duty sets a time where pharmacy customers presenting oxycodone prescriptions would be falsely told that the pharmacy was out of stock. Merrill told investigators that, because the oxycodone customer are aware of the first-come-first served practice, they start to "stagger" in at 8:02 a.m. Tr. 230–31. PIC Merrill even offered the astonishing comment that that she makes a practice of keeping some oxycodone on hand in case it is needed to fill prescriptions for "real pain patients." Tr. 231. The practice of shutting off the pharmacy at a given hour to oxycodone patients was corroborated in a separate interview of another Respondent 5195 pharmacist, named Mark Mascitelli. Tr. 180–82. Lead pharmacist Marie Morrell told investigators that the first-come-first served oxycodone cut off time was sometimes reached between 10:00 a.m. and noon, but could be reached as early as 8:30 a.m. Tr. 188–89.

During the course of the execution of an AIW, GS Carter actually heard one of the Respondent 5195 pharmacy technicians, Arlene Piccerilli falsely tell a customer that the pharmacy was out of stock. Piccerilli explained that she knew this was a lie, but that this was the practice at the store. Tr. 224–25. Tellingly, Piccerilli also related her understanding that pharmacy staff cannot judge whether a prescription is valid, and that such a determination is within the exclusive purview of the prescribing physician. Tr. 226.

Interestingly, PIC Merrill acknowledged that she had perceived patterns in prescribing related to oxycodone, that she did not understand why patients traveled distances of over thirty miles to have their oxycodone prescriptions filled at Respondent 5195, and that she was aware of occasions where her pharmacy dispensed medications to patients with identical addresses who presented identical controlled substance prescriptions issued by the same physician. Tr. 238, 240–41, 301–02. When it was suggested to PIC Merrill that the patients may be selling the oxycodone medications her

pharmacy was dispensing, her response was not surprise, shock, or denial, but merely "I know." Tr. 238. It was revealing that Pharmacist Mascitelli related that he and PIC Merrill had a conversation with CVS supervisor Jennifer Lalani wherein they were instructed to "identify more filters to put in place for oxycodone prescriptions." Tr. 185. Whatever the verification checks that Respondent 5195 urges as sufficient, it seems that at least in the opinion of company supervisor Jennifer Lalani, there was more that could and should have been done.

Interviews with personnel at Respondent 219 were similarly informative. Respondent 219 PIC Paras Priyadarshi and Pharmacist Susan Masso both told investigators that it was not uncommon for their pharmacy customers to request name-brand oxycodone by its slang monikers "the Ms" or "the Blues." Tr. 250, 256, 264. PIC Priyadarshi told investigators that he found nothing remarkable about such requests, or that Respondent 219 was filling a like combination of three controlled substances (oxycodone, alprazolam, and carisoprodol), to the exclusion of other medications, for a high number prescribing physicians. Tr. 247–48. Priyadarshi also indicated that he found nothing unusual about a high number of common ailment diagnosis codes emanating from individual prescribers, or the high concentrations of oxycodone prescriptions emanating from five doctors. Tr. 249–51. Pharmacist Masso told investigators that she did not know why customers at her pharmacy would travel a distance from their residence to see a physician and then another distance to fill the prescription. Tr. 254. Significantly, Appendix D of the *DEA Pharmacist's Manual*, cited by the Respondents and admitted into evidence at their request,¹⁰⁰ lists the following factors among criteria that may indicate that a prescription was not issued for a legitimate medical purpose:

- The prescriber writes significantly more prescriptions (or in larger quantities) compared to other practitioners in the area;
- A number of people appear simultaneously, or within a short time, all bearing similar prescriptions from the same physician;

- People who are not regular patrons or residents of the community, show up with prescriptions from the same physician.

Id. at 66–67; Resp't Ex. 19 at 67. Professor Doering testified that pattern prescribing and distances could be red flags indicating diversion. Tr. 784–85, 791–92, 923. The Respondents' expert witness, Professor Brushwood, agreed that distance can present a red flag requiring resolution. Tr. 1145, 1181, 1194. Remarkably, when asked about the significance of pattern prescribing, Professor Brushwood replied that he "just simply didn't see dispensing patterns * * *" in the data he reviewed. Tr. 1068. Brushwood indicated he was dubious about the value of analyzing trends, as opposed to individual dispensing events. *Id.* However, Professor Brushwood concurred that multiple patients from a single prescriber on a single day with the same combination would be a red flag.

¹⁰⁰ Resp't Ex. 19.

Tr. 1093, 1098, 1119, 1168. Here, however, PIC Priyadarshi's statements to investigators indicate that he had observed distance anomalies and actually accepted the presence of a cognizable prescribing pattern and yet attached no significance to the information.

Notwithstanding the foregoing, the Respondents contend that the red flags identified by Professor Doering are either not red flags or were not red flags at the time the controlled substances were dispensed. Resp'ts Brief at 108–115. Despite the Respondents' arguments, substantial evidence supports the conclusion that the following circumstances presented red flags of diversion during the relevant time period: (1) "pattern prescribing," defined as "prescriptions for the same drugs, the same quantities¹⁰¹ coming in from the same doctor;" Tr. 708, 1119; (2) the prescribing of oxycodone and alprazolam to a patient,¹⁰² Tr. 784, 1170; (3) "prescriptions written by a local prescriber for out-of-state patients," or where the pharmacy is not near the patient or the prescriber,¹⁰³ Tr. 791, 1119; (4) shared addresses by customers presenting on the same day, Tr. 749–50; and (5) the prescribing of controlled substances in general,¹⁰⁴ Tr. 689. These red flags are consistent with Agency and circuit precedent. *See East Main Street Pharmacy*, 75 FR 66149, 66164 (2010) (relying on expert testimony to conclude that the distance traveled by a customer to a pharmacy was a red flag of diversion); *U.S. v. Hammond*, 781 F.2d 1536, 1538 (11th Cir. 1986) (relying on expert testimony to conclude that "the lack of individualized dosing should have * * * alerted [pharmacist] to diversion."); *U.S. v. Veal*, 23 F.3d 985, 988 (6th Cir. 1994) (relying on expert testimony to conclude that prescribing of a "well known combination" of controlled substance would have made "any reasonable pharmacist * * * suspicious.>").

Regarding the dispensing events reviewed by Professor Doering, the Government's

¹⁰¹ While there was conflicting testimony as to whether quantity alone (other than in exceptional circumstances) could constitute a red flag, Tr. 1054, it cannot be disputed that quantity, insofar as it implicates pattern prescribing, is a red flag. Tr. 708, 1119.

¹⁰² The Respondents contend that the oxycodone-alprazolam combination was not a red flag in 2010, when most of the allegedly wrongful dispensing occurred. Respondent's Brief, at 115. Contrary to this contention, DI Langston testified that the combination of oxycodone and Xanax (the brand name for alprazolam) was a red flag of diversion for at least "[a] couple of years ago." Tr. 90.

¹⁰³ The Respondents argue that, because the pill mill problem was not identified until 2010, a South Florida location could not be a red flag because "it is not clear that a reasonable and prudent pharmacist would have appreciated the significance of a Broward County address in 2010." Resp'ts Brief, at 112–113. However, there is no indication that Professor Doering's conclusion that a South Florida physician constituted a red flag was based on the pill mill problem, and not the fact that South Florida is approximately 200 miles from Sanford.

¹⁰⁴ Respondents object to this red flag on the basis that there is no evidence that the prescriptions for "oxycodone or other drugs could not be prescribed legitimately. Resp'ts Brief, at 110. This argument must be rejected for the simple reason that a red flag's overall resolvability does not render it any less a red flag.

⁹⁹ PIC Merrill's explanation that this practice is based on workload considerations (Tr. 229–30) is wholly unpersuasive. No evidence was introduced that oxycodone prescriptions require or receive verification beyond the (minimal) steps afforded to all controlled substances dispensed from the Respondent 219 pharmacy. Yet there is no indication that all controlled substances are rendered unavailable by this policy of fabricating depleted stocks to the customers. The Respondents' reliance upon this yarn in its Brief did not render it more convincing in any respect. Resp't Brief at 35–36.

evidence demonstrated by a preponderance of the evidence that both Respondents dispensed controlled substances in the face of unresolvable and recognizable¹⁰⁵ red flags and satisfied its *prima facie* burden.

Accordingly, consideration of Factors 2 and 4 militate persuasively in favor of the revocation sought by the Government.

Factor Five: Such Other Conduct Which May Threaten the Public Health and Safety

The fifth statutory public interest factor directs consideration of “[s]uch *other conduct* which may threaten the public health and safety.” 21 U.S.C. 823(f)(5) (emphasis supplied). Existing Agency precedent has long held that this factor encompasses “conduct which creates a probable or possible threat (and not only an actual [threat]) to public health and safety.” *Dreszer*, 76 FR at 19434 n.3; *Aruta*, 76 FR at 19420 n.3; *Bosshers*, 76 FR 19403 n.4; *Dreszer*, 76 FR at 19386–87 n.3. Agency precedent has generally embraced the principle that any conduct that is properly the subject of Factor Five must have a nexus to controlled substances and the underlying purposes of the CSA. *Terese*, 76 FR at 46848; *Tony T. Bui, M.D.*, 75 FR 49979, 49989 (2010) (prescribing practices related to a non-controlled substance such as human growth hormone may not provide an independent basis for concluding that a registrant has engaged in conduct which may threaten public health and safety); *cf.*, *Paul Weir Battershell, N.P.*, 76 FR 44359, 44368 n.27 (2011) (although a registrant’s non-compliance with the Food, Drug, and Cosmetic Act is not relevant under Factor Five, consideration of such conduct may properly be considered on the narrow issue of assessing a respondent’s future compliance with the CSA).

Similar “catch all” language is employed by Congress in the CSA related to the Agency’s authorization to regulate controlled substance manufacturing and List I chemical distribution, but the language is by no means identical. 21 U.S.C. 823(d)(6), (h)(5). Under the language utilized by Congress in those provisions, the Agency may consider “such *other factors* as are relevant to and consistent with the public health and safety.” *Id.* (emphasis supplied). In *Holloway Distributors*, 72 FR 42118, 42126 (2007), the Agency held this catch all language to be broader than the language directed at practitioners under “other conduct which

may threaten the public health and safety” utilized in 21 U.S.C. 823(f)(5). In *Holloway*, the Administrator stated that regarding the List I catch all:

[T]he Government is not required to prove that the [r]espondent’s conduct poses a threat to public health and safety to obtain an adverse finding under factor five. *See T. Young*, 71 [FR] at 60572 n.13. Rather, the statutory text directs the consideration of “such other factors as are relevant to and consistent with the public health and safety.” 21 U.S.C. 823(h)(5). This standard thus grants the Attorney General broader discretion than that which applies in the case of other registrants such as practitioners. *See id.* sec. 823(f)(5) (directing consideration of “[s]uch other conduct which may threaten the public health and safety”).

72 FR at 42126.¹⁰⁶ Thus, the Agency has recognized that, while the fifth factor applicable to List I chemical distributors—21 U.S.C. 823(h)(5)—encompasses all “factors,” the Factor Five applied to practitioners—21 U.S.C. 823(f)(5)—considers only “conduct.” However, because section 823(f)(5) only implicates “such *other conduct*,” it necessarily follows that conduct considered in Factors One through Four may not be considered at Factor Five.

In this case, the Government has not alleged or argued reliance upon any conduct which may be properly considered under Factor Five.¹⁰⁷ Accordingly, Factor Five does not weigh for or against revocation.

Recommendation

Based on the foregoing, the Government has established that the Respondents have committed acts that are inconsistent with the public interest. Consideration of the record evidence under the Fourth and Second Factors weighs in favor of revocation. The Respondents dispensed controlled substances where the prescribers were without authorization to prescribe, and under circumstances where a reasonable pharmacist would have concluded that the prescriptions were not issued for a legitimate medical purpose and in the usual course of a professional practice. The red flags that existed were recognized, or should have been, and the convincing expert evidence of record establishes that the red flags were not resolvable by a reasonable and professional pharmacist.

Because the Government has sustained its burden of showing that Respondents committed acts inconsistent with the public interest, the burden shifts to the Respondents to show that they can be entrusted with a DEA registration. A long line of consistent Agency precedent has established that “to rebut the Government’s *prima facie* case, [the Respondents are] required not only to accept responsibility for [the established]

misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the reoccurrence of similar acts.” *Jeri Hassman, M.D.*, 75 FR at 8236; *Hoxie v. DEA*, 419 F.3d 477, 483 (6th Cir. 2005); *Ronald Lynch, M.D.*, 75 FR 78745, 78749 (Respondent’s attempts to minimize misconduct held to undermine acceptance of responsibility); *George Mathew, M.D.*, 75 FR 66138, 66140, 66145, 66148 (2010); *George C. Aycock, M.D.*, 74 FR 17529, 17543 (2009); *Steven M. Abbadessa, D.O.*, 74 FR 10077, 10078 (2009); *Jayam Krishna-Iyer, M.D.*, 74 FR 459, 463 (2009); *Medicine Shoppe-Jonesborough*, 73 FR 364, 387 (2008). The failure to accept responsibility is a condition precedent for the Respondent to prevail once the Government has established its *prima facie* case. *Mathew*, 75 FR at 66140. This feature of the Agency’s interpretation of its statutory mandate on the exercise of its discretionary function under the CSA has been sustained on review. *Mackay*, 664 F.3d at 822.

Notwithstanding ambiguous and nuanced representations to the contrary in the Respondents’ consolidated brief, it is beyond argument that the Respondents’ have not accepted responsibility for the actions that form the basis of the Government’s *prima facie* case. When asked about personnel actions taken in the wake of the DEA investigation of the Respondents’ prescribing practices, CVS Pharmacy Operations V.P. Joseph Abbott made it clear that these actions were not an acknowledgement of any degree fault or mismanagement on the part of the affected employees, but rather a device “to bring in new leadership that would not be distracted by these events.” Tr. 1294; *see also* Resp’t Brief at 126. The message to the employees, the public, and the DEA regulators is clear: there were no missteps on the part of the Respondent pharmacies and their staff, and the personnel changes will reduce “distraction” and allow the enterprise to carry on without admitting fault. “Distraction” in this context appears to be synonymous with “inconvenience,” and inasmuch as the characterization and carefully-chosen explanation was offered by the V.P. of Pharmacy Operations, there can be no doubt that CVS has spoken authoritatively on the matter. Even those portions of the Respondents’ brief that purport to accept responsibility merely set forth vague platitudes extolling the Respondents’ “responsibility to ensure that its pharmacies are compliant with state, federal, and local legislation and requirements and to provide the stores with the tools and information required for them to do so.” Resp’t Brief at 121 (internal quotation marks omitted). The Respondents’ offer of an acknowledgement of their responsibility to adhere to their responsibility as registrants to comply with the law is a wholly inadequate substitute for an acceptance of responsibility under Agency precedent.

The Respondents also assert that their “acceptance of responsibility is demonstrated by their swift and decisive actions in response to the DEA’s execution of the AIWs at the two pharmacies.” *Id.* at 122. Purported remedial measures are, thus, offered as

¹⁰⁵ Inasmuch as Professor Doering’s conclusion as to the unresolvable nature of the foregoing prescriptions rested on a finding of a pattern prescribing red flag, it is clear that knowledge of the presentation of the similar prescriptions on that day must be able to be attributed to the pharmacy. While the knowledge of the prescriptions presented to the pharmacy technicians and pharmacists is attributable to the Respondents, *One Parcel of Land*, 965 F.2d at 316 (“Only knowledge obtained by corporate employees acting with the scope of their employment is imputed to the corporation.”), because Professor Doering’s testimony addressed only the dispensing events *as a whole*, it is unclear at what point the aggregate of the red flags of the customers rendered the red flags unresolvable. That said, it is more than clear that, at the very minimum, the corresponding responsibility was conclusively violated by the time the final dispensing event in each scenario was completed.

¹⁰⁶ In *Bui*, the Agency clarified that “an adverse finding under [Factor Five did not require a] showing that the relevant conduct actually constituted a threat to public safety.” 75 FR 49888 n.12.

¹⁰⁷ In its Brief, the Government acknowledges that Factors 1 and 3 have no application to the present litigation, but make no mention of whether any evidence of record should be evaluated under Factor 5. Gov’t Brief at 58.

acceptance of responsibility. This argument comingles two independent responsibilities under Agency precedent in an impermissible manner. The Agency has framed the dual prongs of the required rebuttal showing in this way:

[T]o rebut the Government's *prima facie* case, [a registrant] is required not only to accept responsibility for [] misconduct, but also to demonstrate what corrective measures [have been] undertaken to prevent the re-occurrence of similar acts. Jayam Krishna-Iyer, 74 [FR] 459, 464 & n.8 (2009). *Both conditions are essential requirements* for rebutting the Government's *prima facie* showing that * * * continuing an existing registration would be "consistent with the public interest." 21 U.S.C. 823(f) (emphasis supplied).

Hassman, M.D., 75 FR at 8236 (emphasis supplied). By pointing to purported corrective measures, the Respondents have offered the second requirement in the place of both.

The decision by the Respondents' to support their staffing decisions based on "distraction" reduction also tacitly accepts the actions of their employees as consistent with company policy. Thus, the value that can be attached here to testimony from Professor Brushwood that corporate guidance issued to CVS field components is consistent with their obligations¹⁰⁸ is less probative than an examination of what the employees actually were doing as evidenced in the record. See *Pharmboy Ventures Unlimited, Inc.*, 77 FR 33770, 33772 n.2 (2012) ("DEA has long held that it can look behind a pharmacy's ownership structure 'to determine who makes decisions concerning the controlled substance business of a pharmacy.'"); *S&S Pharmacy, Inc.*, 46 FR 13051, 13052 (1981) (the corporate pharmacy acts through the agency of its PIC).

The Respondents have also tendered the peculiar concept that as registrants, they are somehow exempt from a demonstration of responsibility acceptance because they are entities, not individual practitioners, or that their corporate status renders the acceptance of responsibility requirement as elusive. The Respondents posit that

because [several Agency decisions cited by the Respondent] involve circumstances where a registrant acted through multiple agents and through a corporate structure as Respondents do here, none of [the cases cited by the Respondents] squarely address the sufficiency of a registrant's acceptance of responsibility, let alone provides a precedent for revoking the Respondents' registrations. Resp't Brief at 123. Because there is a wealth of Agency precedent on point which directly contradicts the Respondents' suggestion that the rebuttal required of corporate registrants lessened by virtue of their status as corporation, it is unnecessary to address the merits of this position. See e.g., *Sun & Lake Pharmacy*, 76 FR at 24529 (pharmacy registration revoked in the absence of acceptance of responsibility); *Liddy's Pharmacy, L.L.C.*, 76 FR at 48897 (application of pharmacy denied in absence of acceptance

of responsibility); *East Main Street Pharmacy*, 75 FR at 66165 (immediate suspension order of pharmacy affirmed in face of absence of acceptance of responsibility); *Medicine Shoppe*, 73 FR at 387 (pharmacy registration revoked in the absence of acceptance of responsibility). Suffice it to say that the Respondents' argument that they unable to discern the nature of the required acceptance of responsibility because they function as corporations is without merit.

Accordingly, in view of the fact that the Government has established its *prima facie*¹⁰⁹ case by a preponderance of the evidence, and the Respondents have declined to accept responsibility,¹¹⁰ the Respondents' Certificates of Registration should be REVOKED¹¹¹ and any pending applications for renewal should be DENIED.

Dated: June 8, 2012

JOHN J. MULROONEY, II

Chief Administrative Law Judge

[FR Doc. 2012-25047 Filed 10-11-12; 8:45 am]

BILLING CODE 4410-09-P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

Holiday CVS, L.L.C., d/b/a CVS/ Pharmacy Nos. 219 and 5195; Denial of Request for Redactions

On August 31, 2012, I issued a Decision and Final Order (hereinafter, Order) revoking the DEA Certificates of Registration issued to Holiday CVS, L.L.C., d/b/a CVS/Pharmacy Nos. 219 and 5195 (hereinafter, Respondents). Prior to publication, counsel for Respondents contacted my staff to request a delay in the publication of the Order in the *Federal Register*, on the basis that it, as well as the Administrative Law Judge's Recommended Decision (R.D.), may contain trade secrets and confidential business information; Respondents sought leave to review the Order and to

¹⁰⁹ Accordingly, the Respondent's motion for a "directed verdict" made (and reserved upon) during the course of the hearing is herein denied.

¹¹⁰ In view of the Respondents' election to avoid acceptance of responsibility, it is not necessary to analyze the adequacy of purported corrective measures offered to demonstrate that similar acts will not occur in the future. See *Hassman, M.D.*, 75 FR at 8236.

¹¹¹ The Respondents have requested that any imposed sanction be limited to the controlled substances that were the subject of the Government's case. Resp'ts Brief at 127-28. In view of the strength of the evidence that shows a pervasive disregard for their duties as registrants, as well as their persistent denial of any measure of culpability, entrusting these registrants with the responsibilities of a DEA COR regarding other dangerous controlled substances would be illogical and unwise. Accordingly, after a considered review of the Respondents' position on the issue, revocation is the sanction that is most consistent with the evidence adduced at the hearing.

file a request for redactions. My staff agreed to the request, and on September 18, 2012, counsel for Respondents filed a letter proposing various redactions to both the Order and the ALJ's R.D.; therein, Respondents set forth four reasons in support of their proposed redactions. Letter of Catherine O'Neill, Esq., to Administrator, DEA (Sept. 18, 2012) (hereinafter, Resp. Req.). Thereafter, the Government was directed to file a response to Respondents' request. On September 29, 2012, the Government filed its Response (hereinafter, Gov. Resp.), objecting to the proposed redactions.

Respondents' proposed redactions involve various portions of the Order and the ALJ's R.D. that discuss the manner in which information was obtained for Respondents' pharmacy information management system. Respondents maintain that this information contains "trade secret[s]" and confidential business information regarding Respondents' business practices," which "is exempt from disclosure under the Freedom of Information Act (FOIA) and [that] its publication will cause significant, and irreparable, harm to their business operations." *Id.* at 1. In addition to these contentions, Respondents argue: (1) That the ALJ's Protective Orders and bench rulings support redaction of the Final Order; (2) that the ALJ's various rulings continue in effect after the termination of the proceeding; and (3) that adoption of the ALJ's Confidentiality Designations is consistent with the manner in which the Agency has treated confidential information in other cases. *Id.* at 3-5.

Opposing the redactions, the Government argues that Respondents have not established that the information at issue involves trade secrets or confidential business information. Gov. Resp. at 1. The Government further argues that the information at issue "is essential to an understanding of the ALJ's Recommended Decision and the Administrator's Final Order." *Id.* at 2. Having carefully reviewed the parties' submissions, I conclude that Respondents have not established their entitlement to the relief sought. See 5 U.S.C. 556(d) ("Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof.").

As noted above, Respondents' first contention is that the proposed redactions involve trade secrets¹ and

¹ Respondents err in contending that the information constitutes a trade secret. As the D.C. Circuit has explained, a trade secret is "a secret, commercially valuable plan, formula, process, or

¹⁰⁸ Tr. 1084.



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U.S. Attorney's Office

Middle District of Florida

FOR IMMEDIATE RELEASE

Wednesday, May 13, 2015

**United States Reaches \$22 Million Settlement Agreement
With CVS For Unlawful Distribution Of Controlled
Substances**

Orlando, FL – United States Attorney A. Lee Bentley, III announces today that CVS Health has agreed to pay \$22 million to resolve allegations that two of its retail stores in the City of Sanford distributed controlled substances based on prescriptions that had not been issued for legitimate medical purposes by a health care provider acting in the usual course of professional practice. CVS acknowledged that its retail pharmacies had a responsibility to dispense only those prescriptions that were issued based on legitimate medical need. CVS further acknowledged that certain of its retail stores dispensed certain controlled substances in a manner not fully consistent with their compliance obligations under the Controlled Substances Act and the related regulations.

The Controlled Substances Act authorizes the United States to seek civil penalties for a pharmacy's failure to fulfill its corresponding responsibility to dispense only those prescriptions that have been issued for a legitimate medical purpose by a health care provider acting in the usual course of professional practice. Knowingly filling an illegitimate prescription subjects a pharmacy to civil penalties under the Controlled Substances Act.

This settlement caps off an investigation that began as part of DEA's crackdown on pill mills in Florida. Prescription drug addicts were travelling to Florida, known as the nation's epicenter for the illegal distribution of prescription drugs, for access to physicians who were prescribing pain medication without regard to medical need and to pharmacies that were filling the prescriptions despite red flags that they were illegitimate. The investigation led to DEA's execution of administrative inspection warrants at two CVS stores in Sanford. As a result, the DEA licenses of both stores were revoked in June 2012.

"Prescription drug abuse continues to be a problem in Florida and throughout the country," said U.S. Attorney Bentley. "We are using all of the tools at our disposal to combat this problem, including civil penalties for pharmacies that fail to comply with the Controlled Substances Act."

This settlement illustrates the United States Attorney's Office efforts to address the wrongdoing that occurred at the height of Florida's pill mill crisis.

This matter was investigated by the Drug Enforcement Administration Diversion Group in Orlando. It was handled by Assistant U.S. Attorney Katherine M. Ho.

Civil Div. I: General (e.g., DOT, FEC, FOIA, FTC (except antitrust), HUD) USAO - Florida, Middle
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Abusive Prescribing of Controlled Substances — A Pharmacy View

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Public health advocates are increasingly focused on illness and deaths caused by inappropriate use of controlled substances — in particular, opioid analgesics. Opioid prescriptions have increased

dramatically, by more than 300% between 1999 and 2010.¹ This increase has led to substantial iatrogenic disease. Most strikingly, the number of deaths due to overdose in the United States increased from 4000 in 1999 to 16,600 in 2010.² Indeed, overdose is now the second-leading cause of accidental death in this country, where more than 2.4 million people were considered opioid abusers in 2010.³

The causes of increases in prescriptions and the prevalence of abuse are manifold. In the mid-1990s, advocates for treatment of chronic pain began arguing that pain was largely undertreated and appropriately exhorted clinicians

to be more liberal in their treatment. In addition, a number of new formulations of opioid agents became available, with purported advantages in analgesia.

But perhaps just as important, inappropriate prescribing has grown. The worst form of such prescribing occurs in so-called pill mills, wherein fully licensed physicians with valid Drug Enforcement Administration (DEA) numbers write prescriptions that provide large quantities of powerful analgesics to individual patients. Such bogus pain clinics cater to younger patients, operate on a cash basis, and draw clients from a broad geographic area. States and the DEA have attempt-

ed to curb pill-mill activities — the best example being Florida's closure of 254 "pain clinics" — but the efficacy of such regulation is unclear.⁴

Pharmacies have a role to play in the oversight of prescriptions for controlled substances, and opioid analgesics in particular. Under the Controlled Substances Act, pharmacists must evaluate patients to ensure the appropriateness of any controlled-substance prescription. In addition, state boards of pharmacy regulate the distribution of opioid analgesics and other controlled substances through the discretion of pharmacists. Yet in the majority of cases of potential abuse, pharmacists face a patient who has a legal prescription from a licensed physician, and they have access to very little other background information. That makes it difficult for individual pharma-

Prescribing Habits of Outlier Prescribers.

Specialty or Type of Clinician	Average Monthly Doses of High-Risk Drugs Prescribed		No. of Outlier Prescribers
	42 Outlier Prescribers	Nonoutlier Prescribers	
Internal medicine	11,314	422	12
Physical medicine	5,599	916	1
Family practice	12,903	575	8
General practice	24,502	462	2
Psychiatry	18,757	213	3
Nurse practitioner	10,715	160	2
Obstetrics and gynecology	11,096	110	3
Physician assistant	5,211	116	1
Pain medicine	8,811	3813	1
Sports medicine	7,025	387	1
Pediatrics	5,524	31	2
Anesthesiology	8,128	1749	1
Geriatric medicine	15,544	493	1
Endocrinology	6,142	116	1
Emergency medicine	7,935	203	2
Preventive medicine	44,397	662	1

cists to use their own partially informed judgment to identify prescriptions that have come from a pill-mill doctor.

Chain pharmacies, however, have the advantage of aggregated information on all prescriptions filled at the chain. At CVS, we recently instituted a program of analysis and actions to limit inappropriate prescribing. Our program was intended to identify and take action against physicians and other prescribers who exhibited extreme patterns of use of “high-risk drugs” relative to other prescribers. We aimed to minimize the potential for falsely identifying legitimate prescribers (false positives), accepting that doing so might result in a failure to identify some suspicious prescribers.

We identified high-risk prescribers by benchmarking them against others on several param-

eters. We used data from submitted prescriptions from March 2010 through January 2012 for hydrocodone, oxycodone, alprazolam, methadone, and carisoprodol. Prescribers were compared with others in the same geographic region who had the same listed specialty. The first parameters were the volume of prescriptions for high-risk drugs and the proportion of the prescriber’s prescriptions that were for such drugs, as compared with the volume and proportion for others in the same specialty and region; the thresholds for suspicion were set at the 98th percentile for volume and the 95th percentile for proportion. Next, prescribers were evaluated with regard to the number of their patients who paid cash for high-risk-drug prescriptions and the percentage of their patients receiving high-risk drugs who were

18 to 35 years of age. In both cases, the thresholds for suspicion were set at the 90th percentile among clinicians in the same region and specialty. Finally, we compared the prescriptions for noncontrolled substances with the prescriptions for controlled substances within the prescriber’s practice on the same parameters. To minimize the possibility that we would suspend dispensing privileges for clinicians who were appropriately treating patients, we attempted to interview physicians whom we’d identified as outliers to ascertain the nature of their practice and their use of controlled substances.

We initially identified 42 outliers (see table) from our database of nearly 1 million prescribers; 17 of the 42 failed to respond to our three letters requesting an interview, despite our indication in the second and third letters that we would stop filling the clinician’s controlled-substance prescriptions if he or she would not speak with us. Eight prescribers sent a written response, and one response was sufficiently detailed to convince us that the prescribing was appropriate. The other seven responses were inadequate, and the prescribers refused to engage in a telephone discussion. Two prescribers retained an attorney, and future conversation occurred through legal channels. We considered these 26 clinicians nonresponsive.

The remaining 15 were contacted by phone, and 5 gave us legitimate reasons why their practice had the identified characteristics — in particular, that each was the only practitioner in a given geographic area caring for patients with chronic pain. The remaining 10 either maintained that their approach was legitimate

but that they didn't have to explain why or averred that they planned to curb their prescribing of narcotics. For all 10 of these clinicians, we decided not to fill their controlled-substance prescriptions through our pharmacy. The same approach was taken for the 26 nonresponsive clinicians. Surprisingly, now 9 months after we stopped filling controlled-substance prescriptions for these clinicians' patients, we've had contact from only 3 of them requesting reinstatement in our pharmacy chain. The table provides details on the 42 outliers' practices, as compared with those of the average prescriber in our database. There was no clear regional concentration of outliers.

Our program is certainly not a comprehensive solution, but it provides some sense of the kind of inappropriate prescribing that is going on in our health care system. We believe that some of these clinicians may be part of pill mills, doing cursory examinations in high volumes of patients, all of whom then receive opioid analgesics. People seeking to abuse these medications will travel long distances to obtain them and often deal in cash only. These patients are generally younger than the average patient with chronic disease. A comprehensive solution would involve the use of a national prescription-

drug-monitoring database that would be used by clinicians at the point of prescribing and by all pharmacies at the point of dispensing. This enhanced view of a patient's controlled-substance history and behaviors would support both prescribers and pharmacists in applying their professional judgment regarding the appropriateness of dispensing a controlled substance.

As we noted, pharmacists have an ethical duty, backed by both federal and state law, to ensure that a prescription for a controlled substance is appropriate. A young person traveling a good distance to fill a prescription and paying cash should raise some concerns for a pharmacist. If the prescription is valid, the pharmacist might have limited grounds on which to deny medication to someone who might be in pain. Yet the DEA has now identified both pharmaceutical distributors and chain pharmacies as part of the problem,⁵ encouraging our industry to develop new programs to reduce inappropriate use.

Our findings provide a lens into the problem we face as a country. Programs providing greater transparency regarding controlled-substance prescribing, such as mandatory use of e-prescribing for all controlled substances and a national, uniform program of prescription-drug monitoring, would

help pharmacists and clinicians target interventions more accurately to help patients who are abusing medications. Some state solutions, such as the Massachusetts database that allows clinicians to look up their own patients' prescriptions, also have merit. Analyses of aggregated data like ours can also target patterns of abuse by both prescribers and patients. Given the growing use of controlled substances and the resulting illness and deaths, more innovative use of transparent data is only prudent.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

From CVS Caremark, Woonsocket, RI.

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Transforming Academic Health Centers for an Uncertain Future

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Academic health centers (AHCs) have long led the advancement of science and medicine by pursuing missions of clinical care, research, and education. AHCs

have been places where important fundamental and translational research is performed and medical innovations are created and tested. Given the dramatic changes

ahead in health care and deteriorating research funding, can this record of achievement continue, or do AHCs in the United States face a growing risk of extinction?